5/23/94

This is a preliminary staff working draft EPA Radiation Site Cleanup Regulation. It is expected to change and is intended to be used primarily to maximize public discussion and comment.

40 CFR part 196

Environmental Protection Agency Radiation Site Cleanup Regulation

AGENCY:

Environmental Protection Agency

ACTION:

Notice of Proposed Rulemaking (NPRM)

SUMMARY:

The U.S. Environmental Protection Agency (EPA) is today proposing regulations that set standards for the remediation of soil, ground water, surface water, and structures at federal facility sites contaminated with radioactive material that will allow these sites to be released for public use. These proposed regulations set standards that will place limits on the radiation doses received by members of the public to an annual committed effective dose of 15 mrem/yr (0.015 mSv/yr) in excess of natural background radiation levels for 1,000 years after the completion of the cleanup.

Exposures to members of the public will be further limited since they will receive exposures no greater than 4 mrem/yr from ground water. This is because site remediation activities must also ensure that ground water affected by a site that is a current or potential source of drinking water does not exceed the Maximum Contaminant Levels (MCLs) developed under the Safe Drinking Water Act for radioactive material. If contaminated ground water can not be restored to a level that does not exceed any of the MCL because the remediation is not technically achievable, active control measures must be adopted to prohibit exposure to the contaminated ground water, the public must be notified of the condition of the site, and regular monitoring must be conducted.

The current MCLs are set at 4 mrem/yr for beta particles, 15 pCi/l for gross Alpha, 5 pCi/l for Radium-228, and 5 pCi/l for Radium-226. When MCLs for radionuclides are changed or added in the future, the Agency intends for those new MCLs to be the ground water protection requirements used for this rule. In July 1991, EPA proposed to revise the MCLs for Radium-228 and Radium-226 to 20 pCi/l, while establishing new MCLs of 300 pCi/l for Radon-222 and 20 ug/l (30 pCi/l) for Uranium.

The committed effective dose of 15 mrem/yr corresponds to a lifetime excess cancer risk of less than 3×10^{-4} over a thirty year exposure. However, it is important to remember that with this 15 mrem/yr dose that EPA is proposing, the Agency is intending to protect the reasonably maximally exposed (RME) individual in the population located on or near a previously contaminated site that has been released for public use after undergoing remediation. The RME is defined as the individual receiving the radiation exposure experienced by the 95th percentile and above of the population at a released site (i.e., the upper five percent exposure level for individuals at the site). Most of the exposed individuals at or near a released site will receive much less exposure than the RME, and therefore will be exposed to much less than 15 mrem/yr.

The goal of these proposed regulations is to expedite the cleanup of sites contaminated with radioactive materials and to promote beneficial reuse of the land. The proposed rule will also ensure that sites contaminated with radioactive materials that are to be released are cleaned up to a consistent level that is protective of human health and the environment and that these standards are applied equitably at all contaminated sites. If a site has not been remediated to allow for unrestricted residential use, the site owner or operator will be required to implement active control measures, such as land use limitations, to ensure that human health and the environment are protected. These active control measures must be selected through a public notice and comment process involving individuals potentially affected by the site cleanup activities. In either the case of a cleanup for unrestricted use, or a combination of site cleanup and active control measures, remedial action must ensure that individuals located at a released site are not exposed to radioactive materials at levels in excess of 15 mrem/yr overall and no more than 4 mrem/yr from ground water. At those sites that are employing active control measures as part of the remedial action to allow release of the sites, the sites must still be cleaned up to levels that ensure that individuals are not exposed to levels of radiation in excess of 75 mrem/yr even in the event that all of the active control measures fail. In addition, if the site is not remediated

to allow for unrestricted residential use, the site will be reevaluated every X years to ensure that radionuclide concentrations in excess of natural background levels at the site do not exceed those levels that could cause any member of the public to receive an annual committed effective dose of 15 mrem/yr and to determine whether further site cleanup is needed.

In addition, all existing and future structures on remediated sites must meet the guidelines of the U.S. EPA Radon Program.

In addition to the requirements being proposed in this rulemaking, EPA is referencing in this preamble, particularly in section IV, existing and future guidances that are currently under development. EPA believes that these guidances will provide "work practices" such as remedial methods and remedial objectives for various site circumstances, that will facilitate site remediations on a consistent basis that is even more protective than those mandated by this rule. EPA expects that additional and updated guidances will be developed in the future that will further facilitate compliance with the remediation of radioactively contaminated sites.

This proposed regulation applies to all federally owned or operated sites and sites licensed by the Nuclear Regulatory Commission (NRC), with the exception of facilities regulated under 40 CFR part 191, Subparts B and C, or 40 CFR part 192, and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund") sites previously cleaned up under 40 CFR part 300 with signed Records of Decision as of the effective date of this rule. Although the radiation cleanup standards proposed in today's rule apply specifically to federal facilities, they may also apply to other CERCLA cleanup activities as "Applicable or Relevant and Appropriate Requirements" (ARARs).

EPA has estimated that there are about 5,000 sites known or presumed to be contaminated with radioactive materials in the United States. Included are sites on EPA's National Priorities List (NPL); under the authority of various Federal agencies, predominantly DOE and DoD; licensed by the NRC and NRC Agreement States; and licensed by States. The volume of radioactively contaminated soil is not known with any degree of certainty and will not be known until cleanup criteria are defined and the sites are remediated. Nevertheless, based on preliminary information, it is estimated that approximately 10^8 cubic meters of contaminated soil are located at Federal facilities and NRC licensees and fall within the scope of this rule.

This proposal is the result of a coordinated effort on the part of EPA, the Nuclear Regulatory Commission, the Department of Energy, and the Department of Defense to develop cleanup standards applicable to all sites under these agencies' jurisdiction and to avoid duplicative or inconsistent cleanup regulations and standards. In addition, EPA is committed to actively solicit public input on this proposed rule. State and local governments, Native American tribes, environmental groups, industry and trade associations, and the public have all participated in developing this proposed rule.

Under a separate rulemaking, EPA also plans to develop regulations to address the management of radioactive waste and to explore the feasibility of recycling or reusing site structures, equipment, and metals after cleanup.

The cleanup regulation proposed today was the subject of an Advanced Notice of Proposed Rulemaking (ANPRM) published on October 21, 1993 (58 FR 54474). EPA has also made an Issues Paper available for public comment that presents issues, approaches, and analyses related to the development of the radiation site cleanup standards in this proposed rule. This Notice of Proposed Rulemaking provides a summary of public comments received by EPA in response to the ANPRM and the Issues Paper.

DATE:

Written comments on this proposed rule should be submitted on or before [**insert date [60 or 90] days after publication in the Federal Register**].

ADDRESSES:

Background Information: The technical information EPA considered in developing these amendments is summarized in a Background Information Document (BID) for 40 CFR part 196. In addition, the potential economic costs and benefits of this rule have been summarized in the form of a Regulatory Impact Analysis (RIA). These documents are available from the Superfund/RCRA Hotline at the address and phone number listed below.

Comments/Docket:

Comments should be submitted, in duplicate, to the docket clerk at the following address: U.S.

Environmental Protection Agency, ATTN: Air and Radiation Docket, Mail Stop 6102, Air Docket No. A-93-27, Room M1500, First Floor Waterside Mall, 401 M Street, S.W., Washington D.C. 20460. The docket may be inspected from 8:00 am to 4:00 pm, Monday through Friday, excluding federal holidays in Room M1500. A reasonable fee may be charged for copies of docket materials.

FOR FURTHER INFORMATION CONTACT:

Further information on other rulemaking activities and copies of documents are available from EPA's Superfund/RCRA Hotline at 800-424-9346 for calls from outside the Washington, DC area and at 703-412-9810 for calls from within the Washington, DC area. For the hearing impaired, the number is 800-553-7672 (toll-free), or 202-260-3000 (local). Information is also available through The Cleanup Regulation Electronic Bulletin Board at 800-700-STDS (800-700-7837) outside the Washington area and 703-790-0825 locally. Specific questions about the issues discussed in this rule should be directed to XXX XXXXX, Radiation Studies Branch, Radiation Studies Division (6603J), Office of Radiation and Indoor Air, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, 202 233-NNNN.

SUPPLEMENTARY INFORMATION

I. BACKGROUND AND GOALS OF TODAY'S PROPOSED RULEMAKING

A. BACKGROUND

1. Need for the Regulation

The exact number of sites contaminated with radioactive material in the United States is unknown, although several

sources estimate that they may number in the thousands. Contaminated sites range in size from corners of laboratories containing short-lived, low-level wastes to sprawling nuclear weapons facilities covering tens of acres containing long-lived, high-level wastes. At these larger facilities, buildings and equipment are often contaminated along with soil, water, and sediments. Many of these sites are also contaminated with non-radioactive hazardous chemicals, making cleanup even more difficult. Protecting human health and the environment from exposure to radiation at these sites presents complex scientific and technical challenges.

Currently, radiation site cleanups are regulated or managed by several federal agencies. The Nuclear Regulatory Commission (NRC) regulates the cleanup of sites operated by its licensees. The Department of Energy (DOE) operates a complex of national research laboratories and weapons facilities and manages the cleanup of contaminated sites within that complex. The Department of Defense (DoD) is also responsible for a diverse range of contaminated sites, including research and development laboratories, military hospitals, reactor operations, and facilities that test and use depleted uranium munitions.

Progress in conducting radioactive site cleanups at many of these sites has been limited and slow. These delays have been caused by several factors. Uncertainty about the nature and extent of contamination at sites is partly to blame, but the lack of specific, enforceable radioactive material cleanup levels has also been a major impediment to progress in many contaminated site cleanups. Under current programs, cleanup standards for radioactive materials are determined on a site-by-site basis by conducting a risk assessment to analyze the extent of the potential threat that the radioactive materials at the site pose to human health. Although these risk assessments are a useful tool for analyzing the extent of contamination at a site, direction is still needed on the level of human health and environmental protection to be achieved at these sites. Currently, differences in risk assessment methods and uncertainty regarding the cleanup level to be achieved can result in differing levels of cleanup for the same radioactive contaminant found at different sites. To address these inconsistencies, a cleanup standard is needed to guide decisions on the type and level of cleanup to be completed at contaminated sites.

The current uncertainty over setting cleanup levels for radioactively contaminated sites increases the expense and time devoted to cleanup planning. For example, uncertainty over the cleanup level to be achieved often translates into delay in determining cleanup approaches to be taken and the technologies to be applied. This, in turn, acts as an impediment to investment in innovative, new cleanup technologies and wastes resources, which could be devoted to cleanup of sites. Time and effort is instead spent on continual planning, and on negotiation over the cleanup levels to be achieved.

These problems have led members of Congress, federal agencies, state governments, the regulated community, and members of the public to call for a more focused approach to setting consistent cleanup requirements. EPA is today proposing to remedy this situation by establishing consistent standards for the remediation of sites contaminated with radioactive materials and for the release of those sites for use by members of the public.

2. Overview of the Current Cleanup Effort

The cleanup standards proposed in this regulation will directly affect radioactive material cleanup activities at many federally owned and operated facilities.

Several federal agencies are involved in radioactive site management and cleanup. EPA, NRC, DOE, and DoD have the primary responsibility for monitoring site cleanups, either as a site owner or operator or as a regulator.

EPA, for example, regulates cleanup activities at contaminated sites designated under the CERCLA program. The parties identified as responsible for remediation activities may include other federal agencies such as DOE and DoD as well as private parties. Although the radiation cleanup standards proposed in today's rule apply specifically to federal facilities, they are potentially suitable for use at other CERCLA cleanup activities as "Applicable or Relevant and Appropriate Requirements" (ARARs).

Currently, 48 sites designated on the Superfund National Priorities List (NPL), under the auspices of CERCLA, are contaminated with radioactive materials, and as many as 38 DoD sites may be added to this number. Of these 48 NPL sites, 16 are owned or operated by DOE. ***[May need to update number of radiation sites on NPL.]***

NRC directs the cleanup of sites operated by its licensees. Generally, such cleanup is tied to the decommissioning of licensed facilities. There are currently approximately 24,000 licensees in the United States, 7,500 of which are licensed directly by NRC, with the remainder licensed through agreements between states and NRC under the Atomic Energy Act of 1954 (AEA), Section 274. NRC estimates that approximately 260 of its 7,500 direct licensees conduct

operations that have the potential to produce substantial radioactive contamination, which will have to be decontaminated to acceptable levels before the sites can be safely released for unrestricted use. These licensees include nuclear power plants, non-power (research and test) reactors, fuel-fabrication plants, uranium hexafluoride production plants, uranium mill facilities, and independent spent fuel storage installations. NRC currently lists 48 radioactively contaminated sites under its Site Decommissioning Management Program.

DOE operates many national research laboratories and weapons production (and storage) facilities. As part of its management obligation, DOE is responsible for the cleanup of any radioactively contaminated sites in these complexes, as well as for cleaning up any sites listed on CERCLA's National Priorities List (NPL) or designated as a CERCLA removal action. DOE has identified 137 sites contaminated with radioactive materials. These sites are further broken down into approximately 500 operable units containing radioactive materials.

DoD is responsible for a diverse range of sites contaminated from defense activities. These activities include research and development laboratories, reactor operations, testing and use of depleted uranium munitions, and military medical care. DoD manages its sites along with sites contaminated with other hazardous wastes under the Defense Environmental Restoration Program (DERP). As of the end of fiscal year 1992, DoD managed a total of 18,795 sites at 1,800 installations under DERP.

It is estimated that of these 18,795 contaminated sites, approximately 100 are contaminated with radioactive materials.

3. Current Radiation Control Regulations

A variety of federal statutes authorize the regulation of radionuclide use and management to protect human health and the environment. Under these statutes, EPA, NRC, and DOE are the federal agencies with primary regulatory authority for the cleanup of radioactively contaminated sites. Several other federal agencies, such as the Department of Defense (DoD) and the Department of Transportation (DOT), also have radioactive waste programs, but they generally are more narrow in scope than those of EPA, NRC, and DOE.

Few radiation protection standards developed under these federal statutes expressly apply to the cleanup of radioactively contaminated sites. The principal exception is EPA's uranium mill tailings standards at 40 CFR part 192. In addition, sites that are listed on the National Priorities List (NPL) and removal actions are cleaned up following the procedures in CERCLA's National Oil and Hazardous Substances Contingency Plan (NCP, 40 CFR part 300).

Although few current radiation protection standards govern site cleanup, several federal regulations and guidances set standards for radiation exposure of the general public and the environment. These standards generally deal with exposure from facility operations. Some of these standards address radiation exposure from all pathways (i.e., all physical routes through which a person can be exposed to radiation: inhalation, ingestion, etc.). Other standards such as EPA's air emissions standards deal with single media and therefore address limited pathways. In addition, EPA, DOE, and NRC have all published standards that limit radiation exposure as the result of radioactive waste management operations.

The major regulations, guidance documents, and advisories issued by these three agencies are summarized below in Exhibit A, along with the radiation protection standards recommended by the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection (NCRP, the U.S. counterpart to the ICRP), and the International Atomic Energy Agency (IAEA).

Section I.A.4 of this preamble discusses current site cleanup practices (i.e., how the regulations are operationally put into practice). A more extensive summary of the current regulatory requirements and current cleanup practices can be found in the Regulatory Impact Analysis (RIA) and Background Information Document (BID). In addition, Section IV.A of this preamble shows how today's proposal is designed to be consistent with the precedents set in existing regulations and guidances that set radiation exposure standards. The following sections summarize in detail the major radioactive material management regulations implemented by EPA, DOE, and NRC, in terms of the standards that apply to radiation site cleanup, standards that apply to radiation exposure during facility operations, and standards that apply to radioactive waste management. Radiation protection guidelines developed by non-governmental bodies are also summarized.

Exhibit A

Summary of Major Radiation Standards, Orders, and Guidance

Agency/ Type of Standard	EPA
Standards that Apply to Radiation Cleanups	Health and Environmental Standards for Uranium and Thorium Mill Tailings (40 CFR part 192) National Oil and Hazardou Substances contingency Plan (NCP-40 CFR 300) (applies to sites on Superfund's national priorities List (NPL) or sites be cleaned up under Superfund's emergency response provisions)
Standards that Apply to Radiation Exposure During Facility Operations	Multiple Pathways EPA Radiation Protection Guidelines for General Population Exposure (applies to all Federal facilities) Media National Emission Standards for Hazardous Air Pollutants (NESHAPS, 40 CFR part 61) (applies to NRC and DOE *National Interim Primary Drinking Water Regulations* (40 CFR part 141, subpart D)
Standards that Apply to Radioactive Waste Management	Health and Environmental Standards for Uranium and Thorium Mill Tailings (40 CFR part 192) (applies to active NRC licensees and inactiv High-Level Waste Rule (40 CFR part 191)

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EPA Regulatory Programs

Under the authority granted in the Atomic Energy Act; Comprehensive Environmental Response, Compensation, and Liability Act; Safe Drinking Water Act; Toxic Substances Control Act; Clean Air Act; Uranium Mill Tailings Radiation Control Act; and other statutes, EPA has issued several regulations and guidances that set radiation exposure standards.

Standards That Apply to Radiation Site Cleanup

Few current EPA regulations expressly govern the cleanup of radioactively-contaminated sites and structures. The principal exception is the health and environmental protection standards for cleanup of mill tailings under Title I of UMTRCA (40 CFR part 192). These standards, apply to specifically designated inactive uranium milling sites and vicinity properties that are being remediated by the DOE. The mill tailings standard limits the concentration of radium-226, radium-228, and thorium within 15 cm of the surface to no more that 5 pCi/g above background levels. They also specify that, when the concentration of radium below 15 cm exceeds a screening level of 15 pCi/g over background levels it must be removed. Part 192 also sets limits on the radon decay product concentration and gamma radiation levels in buildings affected by tailings. In any occupied or habitable building, remedial action should be designed to limit radon decay product concentrations to less than 0.02 Working Levels (WLs). In any case, the radon decay product cannot exceed 0.03 WL, and the level of gamma radiation cannot exceed the background level by more that 20 microroentgens per hour. As discussed in Section II.B., today's proposal would not apply to any uranium mill tailings that have been disposed of under 40 CFR part 192.

Other sites contaminated with radionuclides are currently cleaned up in accordance with the National Oil and Hazardous Substances Contingency Plan (NCP), which outlines the procedures to implement the requirements of CERCLA. These procedures were promulgated under the authority of the Comprehensive Environmental, Response, Compensation, and Liability Act of 1980 (CERCLA), as amended (42 U.S.C. §§ 9601-9657). The NCP has established an acceptable lifetime risk range for carcinogens of 10^{-4} to 10^{-6} for site cleanups conducted under CERCLA. A 1 x 10^{-4} to 1 x 10^{-6} lifetime risk would correspond to a statistical increase in the lifetime cancer incidence rate ranging from one case for every 10,000 people to one case for every million people exposed. CERCLA authorizes EPA to act, consistent with the NCP, to provide for remedial action in response to releases or substantial threats of releases of hazardous substances (including radionuclides) into the environment. Currently, the NPL lists 48 facilities contaminated with radioactive material. As many as 38 DoD sites may be added to this number upon verification of their status. Of the 48 NPL sites, 16 are owned or operated by DOE. ***[May need to update the number of NPL sites.]***

Standards and Guidance that Applies to Protection of the Public Against Radiation Exposure

In 1994, EPA proposed Radiation Protection Guidance (RPG) to assist federal agencies in the formulation of regulations for protecting the general public from exposure to ionizing radiation. Under Executive Order 10831, the EPA Administrator is charged to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." The RPG proposed under this authority is intended to ensure that regulation of exposure to ionizing radiation is carried out by Federal agencies in a consistent and protective manner. This guidance contains the following recommendations:

- 1. There should be no exposure of the general public to ionizing radiation unless it is justified by the expectation of an overall benefit from the activity causing the exposure.
- 2. Individual doses should be maintained As Low As is Reasonably Achievable (ALARA). In other words, exposure to ionizing radiation and releases of radioactive materials should be reduced as far below regulatory limits as is reasonably achievable considering economic, technical, and societal factors, among others.
- 3. Federal agencies should implement the risk-weighted dose limitation system developed by the International Commission on Radiological Protection (ICRP) in 1977. This risk-weighted dose limitations system takes into account the individual contribution of each exposed part of the body to total risk. The risk limit is expressed in the sum of weighted dose equivalent to all parts of the body, called effective dose equivalent, and distributes the dose among various organs and tissues and their assumed relative sensitivity and hereditary effects.
- 4. Authorized limits for sources should be established to ensure that individual and collective doses in populations satisfy the objectives of the guidance. Also, the sources of radon at facilities should conform to authorized limits.
- 5. Members of the public should become constructively involved in the decision-making process and in influencing the public policy issues that affect them.
- 6. Control of exposure of the public should normally be ensured through knowledge of releases from sources and modeling of environmental transport.
- 7. Exceptions to planned exposures of radiation should be made only for highly unusual circumstances. Federal agencies should carefully consider the balance of the guidance, and make a public record of any authorized exception of Recommendation 3.

This radiation protection guidance applies to all appropriate pathways; most other EPA exposure standards apply to single media and thus address a limited number of pathways. For example, EPA has promulgated limits applicable to sources of drinking water under the authority of the Safe Drinking Water Act (41 FR 28404). This rule set Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs) for radionuclides found in drinking water. MCLGs are set at concentration levels at

which no known or anticipated health effects would occur, which is considered to be zero for all carcinogens, including radionuclides. The Act directs EPA to set MCLs as close to MCLGs as possible, taking into consideration technical feasibility and costs. The current MCLs for radionuclides are set at 4 mrem/yr for beta particles, 15 pCi/l for gross Alpha, 5 pCi/l for Radium-228, and 5 pCi/l for Radium-226. In July 1991, EPA proposed to revise the MCLs for Radium-228 and Radium-226 to 20 pCi/liter. As discussed below, EPA is today proposing that remediation of a site must ensure that water that is a current or potential source of drinking water does not exceed MCLs for radionuclides.

Under the Clean Air Act, EPA has promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPS) at 40 CFR part 61, which designate seven categories of substances as hazardous, including radionuclides. Two subparts under Part 61 govern non-radon radionuclide emissions: Subpart H -- concerning DOE facilities, and Subpart I -- concerning NRC-licensees and all Federal facilities not under Subpart H. Neither Subpart applies to facilities subject to 40 CFR part 191, Subpart B, or 40 CFR part 192. Additionally, 40 CFR part 61, Subpart I does not apply to low energy accelerators or any NRC-licensee using radionuclides only in the form of sealed sources. For facilities regulated under Subparts H and I, emissions of radionuclides to the ambient air cannot exceed those amounts which would cause a member of the public to receive an effective dose equivalent exceeding 10 mrem/year. Compliance with the radionuclide emission standards must be measured at all release points having the potential to discharge radionuclides in quantities exceeding one percent of the standard. Facilities regulated under both Subparts H and I follow similar reporting guidelines, which must include an approved calculation of the dose equivalent of radionuclide emissions, specifications for release points and effluent controls, and certain facility specifications. Facilities whose annual reports signal a failure to comply must submit monthly emissions and facility improvement reports until they are in compliance. Subpart I exempts from annual reporting those facilities whose emissions exceed less than 10 percent of the dose standard.

Standards that Apply to Radioactive Waste Management

The EPA mill tailings regulations at 40 CFR part 192 establish a disposal standard of 20 pCi per square meter per second of radon-222 flux for a period of 1000 years for tailings piles. Controls must be designed to be effective for between 200 and 1,000 years and must provide assurance that releases of radon-222 to the atmosphere from residual radioactive material will not exceed an average release rate of 20 $pCi/m^2/s$, or increase the annual average concentration of radon-222 in the air at or above any location outside the disposal site by more than 0.5 pCi/l (40 CFR 192.02). Computational models, theories, and prevalent expert judgment may be used to determine whether a control system design will satisfy the standard.

At 40 CFR part 191, EPA has published Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes ("the High-Level waste rule") (58 FR 66398). This rule sets a dose limit of 15 mrem/yr for all pathways. It does not specify ground water protection standards, but requires that disposal systems meet the MCLs set at 40 CFR part 141 (see discussion above). The high-level waste rule is designed to protect human health and the environment for 10,000 years. In addition to the High-Level Waste Rule, EPA plans to propose a low-level waste rule in the near future.

DOE Programs

In addition to EPA programs, the Department of Energy also administers programs governing radiation exposure during facility operation, and radioactive waste management.

Standards that Apply to Radiation Site Cleanup

Except for those DOE sites covered under the provisions of 40 CFR part 192 (certain DOE mill tailings sites), no specific radiation cleanup standard applies to cleanup at DOE sites contaminated with radionuclides. DOE sites that are listed on the NPL or that are Superfund emergency response sites are subject to the provisions of CERCLA. DOE has published an order, which sets forth its policies and procedures for compliance with Superfund's NCP. DOE orders are the means through which that department identifies management objectives and requirements for DOE personnel and contractors. Like the NCP itself, DOE 5400.4 sets forth an acceptable risk range of 10^{-4} to 10^{-6} In addition, under the Federal Facilities Compliance Act (FFCA), federal facilities are generally required to follow the procedural requirements of the NCP.

Today's proposal applies to remedial actions conducted at sites owned or operated by DOE, except for sites covered under the UMTRCA provisions of 40 CFR part 192 and other sites listed under proposed 40 CFR 196.1(a) (See Section II.B of this preamble for a discussion of the proposed rule's applicability.)

Standards that Apply to Radiation Exposure During Facility Operations

Although only UMTRCA and, in some circumstances, CERCLA, govern the cleanup of DOE facilities, several DOE regulations and orders set radiation protection standards for activities at DOE facilities. Under Order 5400.5 "Radiation Protection of the Public and the Environment,", DOE operates under an agency-wide policy to limit radiation exposure to levels that are As Low As Reasonably Achievable (ALARA). The following factors must be taken into consideration when determining ALARA:

- The maximum dose to the public, where the maximum dose is generally defined as the dose received by an individual within the population distribution at the 99th percentile.
- The collective dose to the population, where the collective dose represents the sum of the individual dose received by each member of the population.
- Alternative processes.
- Doses for each process alternative.
- Costs of each technological alternative.
- Examination of the changes in cost among alternatives.
- Changes in societal impact associated with process alternatives.

DOE 5400.5 sets standards for radiation protection, as well as requirements for operations of DOE and DOE contractors. It sets standards at 100 mrem/yr and provides criteria to reduce exposures to the extent practicable, based on the ALARA principle. In addition, DOE has proposed radiation protection standards at 10 CFR part 834 (56 FR 16268). These proposed standards also incorporate ALARA principles and prescribe additional pathway and activity-specific dose limits, such as 10 mrem/yr for air, 4 mrem/yr for drinking water, and 25 mrem/yr for waste management.

The rule requires that all DOE operations, with the exception of the Naval Nuclear Propulsion Programs, assure that doses resulting from their operations do not exceed 100 mrem/year and that ALARA requirements are implemented. Under the regulation, exposure to radiation, release of radioactive material, and other contamination from a DOE activity will be considered ALARA if the activity is evaluated pursuant to an ALARA program. The ALARA Program should address the potential radiological impact of the

operation on the public and the environment and be approved by DOE. DOE sets forth a procedure for evaluating alternatives to make a judgement with respect to ALARA under Order 5400.5. The factors to be considered under the Order are listed above.

As described above, DOE facilities are also subject to EPA's NESHAPS for radionuclides (40 CFR part 61).

Standards that Apply to Radioactive Waste Management

Disposal of radioactively contaminated wastes at DOE facilities is addressed by DOE 5820.2A, "Radioactive Waste Management." This order establishes policies, guidelines, and minimum requirements by which DOE manages its radioactive, mixed waste, and contaminated facilities. For high-level wastes, the order requires that the wastes be doubly contained, and that waste treatment for high-level wastes be developed and implemented to treat the waste in storage to prepare it for eventual conversion to suitable disposal forms.

The order also requires that low-level wastes must be managed to assure that external exposure to the waste (and concentrations of radioactive material that may be released into media including surface water, ground water, soil, and plants) does not exceed an effective dose equivalent of 25 mrem/yr to any member of the public. The Order also specifies that protection of ground-water resources must be consistent with federal, State, and Local requirements, including MCLs for radionuclides.

In addition, DOE sites are regulated by EPA's high-level waste regulations at 40 CFR part 191.

NRC Programs

The Nuclear Regulatory Commission (NRC) has also promulgated requirements for its licensed facilities.

Standards that Apply to Radiation Site Cleanups

EPA is cooperating with NRC's current efforts to publish criteria for decommissioning NRC-licensed facilities. Under the terms of a Memorandum of Understanding with NRC, EPA will "endeavor to resolve issues of concern to both agencies that relate to the regulation of radionuclides in the environment" (57 FR 54126). EPA believes this dual-track approach provides the best means of ensuring consistency between EPA cleanup regulations and NRC decommissioning standards.

Current NRC license holders (but not facilities licensed by NRC "Agreement States"), are not listed on Superfund's NPL as a matter of policy (48 FR 40661).

Standards that Apply to Radiation Exposure During Facility Operation

Operations at sites licensed by NRC or its Agreement States are subject to the radiation protection standards at 10 CFR part 20. These regulations set a dose limit of 100 mrem/yr plus ALARA. This is equivalent to DOE 5400.5, which set standards for radiation protection of the public and the environment as well as requirements for operations of DOE and DOE contractors. NRC's criteria to determine ALARA are generally the same as DOE's.

Operations at sites licensed by NRC or the Agreement States are also subject to EPA's NESHAPS for radionuclides (40 CFR part 61).

Standards that Apply to Radioactive Waste Management

The disposal of radioactively contaminated wastes by NRC or Agreement State licensees is regulated by NRC's land disposal regulations at 10 CFR part 61. These regulations include procedures, criteria, and terms and conditions that apply to the issuing of licenses for the land disposal of radioactive waste produced by NRC licensees. The disposal of these types of waste applies to surface disposal in the uppermost portion of the earth, or to a depth of approximately 30 meters. Disposing of radioactive waste requires incorporating institutional control and disposal in a manner that provides some form of an intruder barrier.

The disposal of radioactively contaminated wastes by NRC or Agreement State licensees is also regulated by 40 CFR part 192 (for Title II UMTRCA facilities) and EPA's high-level waste disposal rule (40 CFR part 191).

Radiation Protection Guidelines Developed by Non-governmental Bodies

The International Commission on Radiological Protection (ICRP) is an international organization established in 1950 which develops guidance and standards for radiological measurement and protection of workers and the public. ICRP Publication 26 (1977) provides radiation dose limits for routine and planned special exposure of workers. This publication also provides the first explicit attempt to relate and justify permissible radiation exposures with quantitative levels of acceptable risk.

ICRP Publication 60 (1991) recommends:

- Limits on annual effective dose for individuals of 100 mrem, with higher doses allowed in a single year if annual effective dose averaged over 5 years does not exceed 100 mrem.
- Limits on annual equivalent dose of 15 rem to lens of the eye and 50 rem to skin.
- Emphasis on lower dose limits for specific practices (i.e., source constraints) as primary means of implementing the ALARA principle.
- Increase in the risk factor for uniform whole-body irradiation to about 7×10^{-4} per rem and inclusion of weighted non-fatal cancer incidence in the risk factor.

The National Council on Radiation Protection and Measurements (NCRP) is the U.S. counterpart to the ICRP. It is a nonprofit organization chartered by Congress in 1964 to, among other functions, collect, analyze, develop, and disseminate information about radiation protection and radiation measurements, quantities, and units.

NCRP Report No. 91 (1987) recommends annual effective dose limits of 100 mrem for continuous or repeated exposures and 500 mrem for infrequent exposures. These limits do not include exposure to natural background radiation or medical testing exposures.

NCRP Report No. 91 also recommends levels of public exposures at which remedial actions should be undertaken:

- The average annual effective dose equivalent from external exposure from all sources (including background but excluding naturally occurring sources) continuously exceeds 500 mrem. The report indicates that significant internal exposures from sources other than radon should be included in the exposure assessment.
- The average exposure to radon and its decay products exceeds 2 working levels per month.

NCRP Report No. 116 (1992) adopted the recommendations of the ICRP, which specify an annual effective dose equivalent of 100 mrem.

Based in Vienna, Austria, the International Atomic Energy Agency (IAEA) helps to ensure that atomic energy programs in all countries meet certain standards through a program of voluntary compliance and inspection. IAEA also offers guidance on a wide variety of radiological topics, including waste mitigation, minimization, and prevention of radiation risks to the environment.

Principles for exemption from regulatory control of radiation sources and practices have been recommended by IAEA in Safety Series No. 89 (1988). This guide says that a dose which is small in comparison to the dose from natural background should be regarded as posing trivial risk. Using an average individual dose due to natural background of about 200 mrem/yr, the IAEA proposed an effective dose range of 2 - 10 mrem as posing trivial incremental risk.

IAEA Report 99 in its Safety Series (1989) presents criteria and guidance for the underground disposal of nuclear wastes. It states that for releases from a repository, the upper bound dose should be less than an annual average dose of 100 mrem for prolonged exposures for maximum exposed individuals. It also suggests an upper bound risk of 10^{-5} per year for an individual for disruptive events.

4. Current Site Cleanup Programs

[This section will be updated based on continuing RIA research]

Environmental Protection Agency (Superfund Sites)

EPA cleans up or oversees cleanup of uncontrolled hazardous waste sites under the Superfund Program. Superfund was established by the Compensation Environmental Response and Liability Act (CERCLA) of 1980 to perform removal actions and remedial actions. Removal actions involve activities needed to remove or cleanup hazardous substances released to the environment, activities needed to monitor, assess, and evaluate the release or threat of release, and the disposal of removed material. Removal actions may also include limiting access to sites, provision of alternative water supplies, and temporary evacuation and housing of threatened individuals. Remedial actions involve permanent remedies to control hazardous substance releases, which are taken instead of or in addition to removal actions. Remedial actions can involve storage, confinement, or covering of hazardous substances; neutralization, recycling, segregation, or other disposal actions for released hazardous substances; and monitoring or other post-remedial site control activities to ensure the protection of human health and the environment. EPA may conduct a removal action at any time that a release of a hazardous substance poses an "imminent and substantial danger" according to CERCLA and the National Contingency Plan (NCP). Remedial action under CERCLA occurs primarily at National Priority List (NPL) sites, which are those abandoned hazardous substance sites that EPA has determined pose the greatest risk to human health and the environment. Federally funded remedial actions are limited to those sites on the NPL.

Cleanup Levels

In selecting a remedy at an NPL site, the NCP requires that two "threshold criteria" be met: 1) cleanup must be protective of human health and the environment, and 2) cleanup must meet applicable or relevant and appropriate requirements (ARARs), or justify a waiver. EPA has generally considered cleanup to be protective if it results in a lifetime excess cancer incidence risk range of between 10^{-4} and 10^{-6} (for carcinogens) and a hazard index of less than 1 for noncarcinogens. Since there is no single set of regulations and guidelines prescribing the cleanup of sites containing radioactive material, ARARs are likely to vary from site to site. The selection of ARARs involves site-specific analysis.

Restricted v. Unrestricted Use

The NCP allows EPA to consider institutional controls, such as water use and deed restrictions, in assessing risks posed by the site and in investigating appropriate remedies. Superfund-financed remedial actions cannot begin without assurances from the State that it will ensure that institutional controls implemented as part of the remedial action are in place and reliable and will remain in place after initiation of operation and maintenance. (Final Rule Preamble, 55 FR 8706 and 55 FR 8854; NCP 300.510(c)(1); CERCLA 104(c)(3))

The NCP provides limited guidance to EPA on when to restrict the use of a Superfund site. However, the NCP directs EPA not to use institutional controls as a substitute for active response measures; institutional controls are to be used as the site remedy only if more active measures are not feasible.

Nuclear Regulatory Commission

The Nuclear Regulatory Commission (NRC) replaced the Atomic Energy Commission (AEC) as a result of the Energy Reorganization Act of 1974. This Act and the Atomic Energy Act of 1954, as amended, provide the current foundation for regulating the nuclear power industry. However, NRC sites may also be cleaned up using CERCLA guidelines.

Cleanup Levels

NRC is in the process of developing generic standards for sites contaminated with radioactive wastes. Until these are made final, the Commission will apply existing cleanup standards on a site-by-site basis and will emphasize residual contamination levels that are As Low As Reasonable Achievable (ALARA). These contamination levels are set with the expectation that exposures will be further reduced to levels that are ALARA, taking into account various factors of practical implementation (cost versus benefit) and socioeconomic considerations.

Implementing ALARA may be difficult, because no specific guidance has been established for residual contamination criteria. In addition, there are different levels of "clean"

specified in the regulations for various pathways: ground water, soil, and buildings. In the past, licensees were required to reduce doses to levels below the regulatory requirements, as long as it was cost-effective to do so, as an application of ALARA.

Restricted v. Unrestricted Use

The decommissioning regulations for NRC-licensed sites under 10 CFR parts 30, 40, 50, 70, and 72 define decommissioning as removing a facility from service, reducing the residual radioactivity to a level that will permit release of the facility for unrestricted uses, and termination of the license. For most sites this will be possible, but there are some instances where reducing the radioactivity may be difficult or costly to achieve. Some types of contamination, such as mixed wastes consisting of both chemical and radioactive wastes, can cause a greater risk to human health and the environment through remediation than by restricting access to and monitoring the site indefinitely. For example, mixed wastes containing short-lived radionuclides will decay rapidly; therefore, if left in place, the waste will become less hazardous over time.

Uranium mill tailings sites are not expected to be impacted by the pending regulations because uranium mill tailings are regulated by EPA under the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978. This Act requires the cooperation of NRC, EPA, and DOE to provide for the disposal, long-term stabilization, and control of uranium tailings.

As an alternative to decommissioning a site, the Commission may authorize a licensee to relinquish control of a contaminated facility if one of the following circumstances applies: razing a building, transferring the property to another organization that would use the facility for a similar purpose, or conversion of the facility to long term storage or standby status.

Department of Energy

The identification, assessment, and cleanup of radioactively contaminated DOE facilities is managed by the Environmental Restoration Program within DOE's Office of Environmental Restoration and Waste Management (EM). The Program is responsible for two types of activities: Decontamination and Decommissioning (D&D) and Remedial Action (RA). D&D involves the decontamination for reuse or the dismantling of surplus nuclear facilities, such as reactors, hot cells, storage tanks, and other facilities. Most of the approximately 500 facilities requiring D&D have not suffered releases, so remediation of soil and ground water contamination is not required. For the most part, RA involves the cleanup of facilities that have contaminated soil and ground water. Currently, DOE has inventoried 137 facilities requiring remediation for radioactive materials.

DOE sites that are on the Superfund National Priorities List (NPL) are subject to EPA CERCLA regulations. DOE responds to releases of hazardous substances at all sites under its jurisdiction in accordance with the provisions of CERCLA, as amended and, for those facilities on the NPL, in accordance with the NCP and Executive Order 12580. At these sites, DOE assumes lead authority for cleaning up the site, but follows CERCLA procedures. EPA sets the cleanup level and oversees sight assessment and cleanup. EPA must approve DOE procedures and cleanup.

To comply with the CERCLA requirements, DOE will enter into Interagency Agreements (IAGs) and/or Federal Facility Agreements (FFAs) with federal, state, and local entities for the execution of RI/FSs and remedial actions. Through the use of IAGs and FFAs, DOE can ensure that corrective actions carried out under other authorities (e.g., RCRA or state laws) are consistent with the NCP and, therefore, satisfy CERCLA requirements. Where DOE remedial actions under CERCLA trigger the requirements in NEPA, DOE must integrate the procedural and documentation requirements of CERCLA and NEPA, wherever practical.

For facilities that are not on the NPL and that require a cleanup action, DOE must conduct a corrective action pursuant to RCRA (at facilities with RCRA permitted units) or other applicable authorities. The RCRA and CERCLA programs follow roughly parallel procedures in responding to releases. Both programs provide for an investigation and formal study of long-term cleanup options, including the remedial investigation/feasibility study (RI/FS) under CERCLA and the corrective measures study (CMS) under RCRA. When these analyses are completed, both provide for formal selection of a remedy. DOE sites not on the NPL include national laboratories; nuclear weapons production and testing facilities; and privately owned sites used by the former Atomic Energy Commission and the Manhattan Engineering District for research, processing, and production of uranium and thorium and for storage of residues.

The Environmental Restoration Program also carries out remedial action under the Formerly Utilized Sites Remedial Action Program (FUSRAP) and the Uranium Mill Tailings Remedial Action (UMTRA) Project. FUSRAP was established to identify, characterize, and remediate contamination at sites formerly used by the Manhattan Engineering District and the Atomic Energy Commission. UMTRA is charged with the cleanup of uranium mill tailings at uranium processing sites.

Cleanup Levels

With the exception of UMTRCA sites, which are cleaned up according to the standards in 40 CFR 192, radioactive material clean-up levels at DOE sites are determined on a case-by-case basis. These cleanup levels are generally negotiated with EPA and appropriate state agencies, as part of a site's Federal Facility Agreement (FFA). All sites are subject to an agency-wide policy of reducing exposure to radiation to ALARA levels. If a site will be released for unrestricted use, the intent of the ALARA policy is to reduce residual contamination to a level that is as far below the specified guidelines as reasonable. If a site cannot be released for unrestricted use, institutional controls must be established to restrict site access so that exposure is reduced to an ALARA level.

The specific approach taken in determining the appropriate cleanup level at a unit depends on the type of DOE site under consideration. DOE sites containing units with CERCLA hazardous substances are managed according to CERCLA procedures, while active units used to manage hazardous wastes may be closed or may undergo corrective action using RCRA procedures. DOE uses the site-specific Federal Facility Agreements with EPA and individual states to determine appropriate cleanup requirements at its sites.

For DOE sites managed under FUSRAP and the Surplus Facilities Management Program, DOE's general procedure is to begin with the dose limits and generic guidelines developed for these programs and to then determine if more strict ALARA site-specific cleanup levels are feasible. If a determination is made that the dose limits and generic or site-specific guidelines cannot be met at a particular site, then the general procedure is to impose institutional controls limiting the future access to the site until the exposure to the public is ALARA. A "guideline" specifies an acceptable level of radioactivity or radioactive material for unrestricted use of the site. DOE uses both generic guidelines and site-specific guidelines. Generic guidelines are based on existing radiation protection standards used by EPA and NRC. When generic guidelines are determined to be inappropriate, site-specific guidelines are derived from basic dose limits using pathways analyses. An "authorized limit" specifies the clean-up level that must be achieved at the conclusion of remedial action. Authorized limits are generally set equal to guideline values, except when an evaluation of site-specific data indicates that the guidelines are not appropriate for that site. In these cases, supplemental limits or exceptions to authorized limits may be required for all or part of the site.

5. Summary of Baseline Analysis

[This section will be updated based on continuing RIA research and analysis of "Justification for Excavation".]

As part of the work completed in support of this proposed rulemaking, EPA conducted an analysis of the baseline cleanup practices and approaches currently being followed for establishing cleanup requirements at DOE, NRC, DoD, and CERCLA sites. These sites are scheduled for remediation regardless of whether the proposed rule is adopted; therefore, the term "baseline" refers to those cleanup activities that will take place in the absence of the proposed rule. Knowledge of the baseline practices is crucial in determining the likely impact of the proposed rule because only the incremental costs and benefits above and beyond those that would accrue from the baseline activities are attributable to the proposed standard.

The Agency investigated those aspects of the remediation process that are likely to be affected by the proposed rule in its baseline analysis. It is unnecessary to examine those practices that will be unaffected by the proposed regulation because there will be no new costs or benefits associated with them as a result of the proposed regulation. The current site management practices that EPA expects may change when the proposed rule is enacted include the following:

- Cost of site and risk assessment: Uniform cleanup standards may reduce or eliminate the need for the detailed risk assessments currently conducted, in part, to determine appropriate cleanup levels.
- Legal costs: Costs associated with negotiation and litigation over whether a particular cleanup standard for a site is appropriate may be eliminated with the adoption of the proposed regulation.
- Timing: Site cleanups may occur faster than they would under baseline conditions because of less exhaustive risk assessments and legal proceedings.
- Cleanup levels: Imposition of a uniform national standard may result in stricter cleanup levels being achieved in some sites and possibly more lenient cleanup levels achieved in other sites than would have been the case in the absence of the rule.
- Cleanup technologies: The proposed regulation may encourage the development and use of both innovative and currently available technologies that may not otherwise occur.
- Storage, transportation, and disposal: The proposed regulation may lead to a different volume of radioactive waste being stored, transported, and/or disposed of and at a different time schedule than would occur under baseline conditions. If, for example, the cleanup standard causes sites to be cleaned up faster, the demand for waste disposal sites may be greater than would otherwise prevail. Alternatively, the proposed regulation may lead to greater use of currently available waste-volume reduction technologies during clean-up than would have occurred in the absence of the standard, leading to a lower demand for waste-disposal services.

EPA's baseline analysis demonstrates that the extent to which these activities are affected by the proposed rule varies widely by site. In sites located in densely populated metropolitan areas, for example, the savings in litigation and negotiation costs resulting from the proposed standard is estimated to be higher than for sites in sparsely populated rural areas.

6. Chronology of EPA Regulatory Activities Associated with Today's Rulemaking

Today's proposed rulemaking is a culmination of EPA research, consultation, and regulatory development activities extending over the past ten years.

On June 18, 1986, EPA published an Advanced Notice of Proposed Rulemaking (ANPRM) titled "Radiation Protection Criteria for Cleanup of Land and Facilities Contaminated with Residual Radioactive Materials" (51 FR 22264). Many of the issues raised in that previous ANPRM are similar to those addressed in today's proposal, including the level of risk that a proposed regulation should achieve to ensure protection of human health and the environment after a cleanup, and the scope and applicability of a proposed rule with regard to specific waste types, facility types, and environmental media. EPA received ***[to be added]*** comments in response to the June 18, 1986 ANPRM. The comments principally addressed ***[to be added]***.

On March 16, 1992, EPA and the Nuclear Regulatory Commission signed a memorandum of Understanding (MOU) to "establish a basic framework within which EPA and NRC will endeavor to resolve issues of concern to both agencies that relate to the regulation of radionuclides in the environment." This MOU governs today's proposed EPA regulations. The MOU defines the roles responsibilities, and separate rulemaking activities of each agency concerning regulations that affect NRC licensees and NRC-licensed facilities and radioactive materials. This approach provides the best means to help ensure that EPA cleanup regulations and NRC decommissioning standards are consistent.

EPA has continued to recognize the need for consistent radioactive material cleanup standards for contaminated sites because such standards are necessary to promote certainty in cleanup activities, reduce costs associated with site investigations and cleanup level negotiations, and ensure adequate public involvement and equity in protecting public health and the environment.

As a result, EPA published a second ANPRM on October 21, 1993, titled "Radiation Site Cleanup Regulations." This ANPRM announced that EPA was developing regulations that will set forth requirements for cleanup levels for sites contaminated with radionuclides. The ANPRM specified this would be designed to protect human health and the environment from exposure to ionizing radiation, and will be applicable to sites contaminated with radioactive material subject to the Atomic Energy Act (AEA) and to sites covered under the authority of the comprehensive Environmental Response, Compensation and Liability Act (i.e., Superfund sites), including but not limited to Federal facilities.

The October 21, 1993, ANPRM requested comment on several issues related to the cleanup regulations, including the level of protection to be achieved, consistency with existing regulations, regulatory approaches encompassing single dose or risk limits or tables of default media and radionuclide-specific concentration limits, practicality issues concerning remediation technologies and cleanup costs, applicability to naturally occurring and accelerator-produced radioactive material (NARM) and diffuse naturally occurring radioactive materials (NORM), and approaches for addressing mixed waste. In addition to cleanup issues, the ANPRM also requested comment on issues relating to radioactive waste management and recycling/reuse of contaminated structures, equipment, and metal. The comments received in response to this ANPRM are summarized in Section IV of this preamble.

[add ANPRM comment summary]

As part of the development of this proposed rulemaking, EPA has been committed to active communication with the public, especially with those interested parties potentially affected by the rule. In particular, EPA has actively disseminated information concerning this proposed rulemaking through publication of an Issues Paper and brochures, and establishment of a Cleanup Regulation Electronic Bulletin Board. The Issues Paper presents issues, approaches, and analyses related to the development of the radiation site cleanup standard and is available through the RCRA/Superfund Hotline at 800-424-9346 for calls from outside the Washington, DC area and at 703-412-9810 for calls

from within the Washington, DC area. For the hearing-impaired, the number is 800-553-7672 (toll-free), or 202-260-3000 (local). The Cleanup Regulation Electronic Bulletin Board can be accessed at 800-700-STDS (800-700-7837) outside the Washington, DC area and at 703-790-0825 within the Washington, DC metropolitan area.

In addition to outreach activities geared toward the general public, EPA is also seeking input from individuals actively involved in environmental and radioactive material management through the establishment of a subcommittee under the auspices of the National Advisory Council for Environmental Policy and Technology (NACEPT). NACEPT is chartered under the Federal Advisory Committee Act and provides extramural environmental policy information and advice to the EPA Administrator and other Agency officials. Membership on the subcommittee established to advise on today's proposal consists of individuals from a wide variety of governmental agencies, industry, and public interest groups, thereby ensuring balanced representation. The NACEPT Subcommittee has met twice and conducted a teleconference call.

During the initial NACEPT Subcommittee on Radiation Site Cleanup Regulations held in October 1993, the following major issues were raised:

- The radiation site cleanup standard should be measurable and verifiable.
- The rule should consider local statutes and cultural needs, and involve all levels of government, as well as the public, early in the process.
- EPA should consider the rule's impact on the current waste management infrastructure.
- The cleanup standards should be developed in the context of other regulations.

The subcommittee members did not agree on an appropriate risk level or whether or not the regulation should be a single number or a range. There was consensus that the regulation should be protective, verifiable, and measurable, but there was no consensus on prioritizing these goals. The subcommittee also recognized that institutional controls would be necessary at sites with restricted uses. Members discussed the issues of enforceability, local community responsibility, and maintaining the effectiveness of controls over time.

In February 1994, the NACEPT Subcommittee held a second meeting via conference call. The meeting addressed the following major topics:

- Cleanup levels
- Land use
- Site-specific public participation
- Preliminary issues on waste disposal

The subcommittee members supported a risk-based standard and applauded the use of a single target. Subcommittee members agreed that consistency with other regulations should be considered, however, there was general agreement that this should not be the overriding factor in the decision on the appropriate cleanup level. Subcommittee members asserted that public participation is a crucial component of site cleanup. Members indicated that a structure for public participation is important, including a structure for continuing participation following remediation at sites where future uses are restricted. The subcommittee discussed the use of site-specific advisory boards (SSABs), but also acknowledged that some coordination is needed to avoid a proliferation of advisory groups.

The NACEPT subcommittee comments are further summarized in Section IV.

EPA has also sought comment from its Science Advisory Board (SAB) concerning approaches for developing and implementing a radioactive material cleanup standard. ***[add information concerning presentations to SAB and comments received]***

Finally, EPA is working to ensure that the development and implementation of this proposed rule is coordinated with other Federal agencies involved in radioactive material management. The AEA and Reorganization Plan No. 3 specify that the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC) have the authority to implement and enforce these standards at sites under their jurisdiction. The President's message to Congress upon transmitting Reorganization Plan No. 3 indicates that, to avoid duplicative efforts at NRC-licensed facilities, NRC would retain responsibility to enforce the standards. This message to Congress, in addition to the Reorganization Plan itself, the AEA, and the MOU between EPA and NRC (57 FR 54127), reflect the recurring intent of both Congress and the Executive Branch that federal agencies:

Avoid setting duplicative or piecemeal radiation protection regulations, and

Coordinate the implementation and enforcement of generally applicable radiation protection standards.

For example, the President's Message states, "The Atomic Energy Commission's authority to set standards for the protection of the general environment from radioactive material would be transferred to the Environmental Protection Agency . . . AEC [now NRC] would retain responsibility for the implementation and enforcement of radiation standards through its licensing authority."

In addition, the AEA provides other examples in which EPA and NRC are expected to coordinate the exercise of their respective authorities to protect human health and the environment from radioactive materials. For example, NRC must ensure that the management of byproduct material conforms with the standards promulgated by EPA under Section 275 of the AEA. This is consistent with the approach taken in the Reorganization Plan: EPA and NRC's authority to protect health and the environment from risks associated with byproduct material is intended to be a coordinated effort rather than duplicative effort.

This intent that the agencies coordinate implementation of cleanup efforts was also reflected in the November 1992 MOU between EPA and NRC. The MOU shows that NRC and EPA have agreed to minimize duplicative or piecemeal regulations and "ensure that standards and regulations when issued can be effectively implemented." It also specifies procedures for coordinating standards-setting and implementation responsibilities, and reiterates the understanding that EPA issues generally applicable standards under the Reorganization Plan, and NRC implements them through its licensing and regulatory authority.

B. GOALS OF THIS PROPOSED RULEMAKING

Today's proposed rulemaking has four main goals.

- First, EPA is proposing cleanup standards that are fully protective of human health and the environment. EPA acknowledges that cleanup of radioactive materials to achieve a standard of 15 mrem/yr for unrestricted use for all exposure pathways is not always technically feasible. As a result, EPA is also allowing for alternative site uses and the coupling of site cleanup with active control measures to achieve the dose limit of 15 mrem/yr, which is the same risk limit applied for unrestricted use of a site. In this way, EPA is proposing to maintain a cleanup standard that is fully protective of human health while allowing for flexibility in

site-specific cleanup approaches. Furthermore, requiring the protection and remediation of ground-water affected by contaminated sites to Maximum Contaminant Levels for radionuclides is fully consistent with the human health protection goals specified under the AEA and Safe Drinking Water Act. In addition, EPA has concluded that the cleanup standard proposed today is also protective of other environmental receptors typically found at contaminated sites, including fish, wildlife, birds, and plants.

- Second, defined cleanup standards provide greater certainty for concerned public site owners and operators in terms of the cleanup goals they are to achieve. This certainty will reduce transaction costs by lessening or eliminating the time and resources previously invested in conducting pre-cleanup assessments and negotiating a cleanup goal.
- Third, the proposed rule promotes meaningful communication with the public to inform individuals of activities at contaminated sites and to consult with individuals affected by cleanups when alternative site uses and active control measures are proposed. In this way, the public will be made aware of the human health risks associated with the sites and will be consulted when radioactive materials will remain at the sites at levels above those suitable for unrestricted residential use. Furthermore, the use of a consistent radioactive material cleanup standard for all sites ensures that protective cleanup levels will be achieved in spite of a site's location. In this way, all ethnic, socioeconomic, and racial groups located near contaminated sites undergoing cleanup will be protected equally.
- Finally, EPA is promoting the use of innovative cleanup, waste minimization, and pollution prevention technologies. By expressing the cleanup standard as a dose limit to be achieved for the overall site rather than as a concentration standard to be achieved in the soil or other media, EPA is promoting the use of the most effective approaches to achieving the cleanup level, which should result in the generation of less waste material for ultimate disposal. Furthermore, EPA is not specifying the cleanup technologies to be used at contaminated sites. As a result, EPA is leaving the regulated community free to develop and implement innovative and cost effective approaches for site cleanup. Over time, certain technologies may become recognized as best able to achieve the cleanup standards, and, as a result, will become more cost-effective through mass production and marketing of the technologies.

In sum, through today's proposal, EPA is establishing consistent cleanup standards that protect human health and the environment. These standards will be implemented equitably and will promote waste minimization/pollution prevention, and the use of currently available innovative cleanup/treatment technologies.

C. RELATIONSHIP TO WASTE MANAGEMENT RULE

In a companion rulemaking effort, EPA is developing proposed regulations to establish uniform standards governing the management of radioactive waste materials, including those waste materials generated during radioactive site cleanups. In the October 21, 1993 ANPRM, EPA requested specific comment on radioactive waste management issues.

The pending radioactive waste management rules will set standards that provide for the protection of human health and the environment and that promote cost-effective and implementable approaches to radioactive waste management (including disposal). These regulations will apply to wastes generated at facilities that are being cleaned up and to facilities that treat, store, and dispose of radioactive wastes.

The issues that EPA are currently evaluating with regard to radioactive waste management include the scope and applicability of the waste management rules and the relationship between regulatory standards and guidance to deal with waste treatment, storage, and disposal activities. The Agency is also evaluating how today's proposal will affect the volumes of wastes generated during radioactive site cleanup in relation to the availability of waste disposal sites and their capacities. The Agency recognizes that given the potential inadequacy of existing licensed disposal sites to accommodate the volumes of radioactive waste anticipated from site cleanups, alternative waste management options should be considered including the use of above-ground onsite retrievable storage. These and other issues currently under review by the Agency will be presented in a Radioactive Waste Management Issues Paper to be published by EPA in the near future. The Agency anticipates publishing a proposed radioactive waste management rule in the Fall of 1995.

II. DESCRIPTION OF THE PROPOSED RULEMAKING

A. STATUTORY AUTHORITY

[This section will be expanded with the assistance of OGC.]

1. Atomic Energy Act

EPA is proposing today's rule pursuant to the Agency's authority under the Atomic Energy Act (AEA) of 1954, as amended (42 U.S.C § 2011 et seq.) and Reorganization Plan No. 3 of 1970 (35 FR 15623). Reorganization Plan No. 3 established the Environmental Protection Agency (EPA) and provided the Agency with certain authorities previously vested in the Atomic Energy Commission. Specifically, the Plan provided EPA with the authority to establish "generally applicable environmental standards for the protection of the general environment from radioactive material." As stated in the Reorganization Plan, "standards mean limits on radiation exposures or levels, or concentrations and/or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive materials." These generally applicable standards can include, among other things, limits on human exposure to radioactive material and cleanup levels for allowable concentrations or quantities of radioactively contaminated material in soil and other media.

2. Relationship to CERCLA

Today's proposed cleanup standards for radioactive materials specifically apply to Federally owned or operated facilities and NRC licensees. In addition, because the standards proposed today address materials that are "hazardous substances, pollutants, and contaminants" under CERCLA and because these standards are generally applicable, are protective of health and the environment, and are enforceable by Federal agencies, these standards may also be applied as "Applicable or Relevant and Appropriate Requirements" (ARARs) under CERCLA authority.

Under CERCLA, if any "hazardous substances, pollutants, or contaminants" will remain onsite once a remedial action is completed, and if any environmental standard "is legally applicable . . . or is relevant and appropriate under the circumstances," then the remedial action must require "a level or standard of control for such hazardous substance or pollutant or contaminant which at least attains such legally applicable or relevant and appropriate standard, requirement, criteria, or limitation." Because radionuclides are "hazardous substances, pollutants, and contaminants" under CERCLA and because EPA's generally applicable standards are protective of health and the environment and are enforceable by federal agencies, today's proposed radioactive material cleanup standards may be used as ARARs under CERCLA.

3. Relationship to RCRA

[To be added.]

B. APPLICABILITY

Today's proposed rulemaking sets standards for the cleanup of radioactive materials found at federally owned or operated facilities, Nuclear Regulatory Commission-licensed sites, Department of Defense-owned or operated facilities, or other sites owned or operated by the federal government. However, the NRC plans to publish decommissioning standards, and if EPA determines that NRC's regulatory program achieves a sufficient level of protection of the public health and environment, EPA will propose in the Federal Register that NRC licensees be exempted from these proposed standards. There is additional discussion in Section II(E) of this preamble on a Memorandum of Understanding signed between EPA and the NRC which governs the proposed EPA regulations and the proposed NRC decommissioning standards. Sites remediated under CERCLA authority may also be required to comply with the cleanup standards in today's proposal because of their status as an Applicable or Relevant and Appropriate Requirement (ARAR). Disposal at facilities regulated under 40 CFR part 191, uranium mill tailings piles disposed of under 40 CFR part 192, and CERCLA sites remediated under 40 CFR part 300 are not addressed by the proposed cleanup standards.

The characteristics of the sites affected by today's proposal are summarized below.

1. DOE Sites

DOE is responsible for cleaning up more than 100 contaminated facilities in 36 states and territories. Radioactive contamination at these facilities ranges from small, slightly contaminated laboratory rooms to large, complex, highly contaminated processing plants, as well as surrounding contaminated lands. In addition to sites that are government-owned, DOE has responsibility for some sites that were formerly used in government operations or for the benefit of the government. Active sites are under the Waste Operations programs, and inactive or surplus sites are under the Environmental Restoration program. Waste management includes the treatment, storage, and disposal of high-level, transuranic, low-level chemically hazardous, mixed, and solid wastes.

The environmental restoration program includes remedial actions and decontamination and decommissioning. Remedial actions are primarily concerned with all aspects of the assessment and cleanup of inactive potential release sites; decontamination and decommissioning are primarily concerned with the safe caretaking of radioactive and hazardous materials at surplus nuclear facilities. Most problems addressed in environmental restoration are the result of past waste management practices that, although considered acceptable at the time, do not meet the more stringent standards for protection of human health and the environment included in today's proposal.

The types of sites addressed under the DOE environmental restoration program include:

- Diversified Laboratories - There are 10 major national laboratories and four more focused laboratories that conduct diversified research programs. Radioactive contamination is generally widespread at these complexes. For example, the Hanford, Washington site has identified approximately 1,100 waste subsites requiring contamination. Most of these subsites were contaminated by onsite storage or soil disposal of low-level radioactive and chemical waste, resulting primarily form the production and chemical processing of plutonium.
- Nuclear Materials Production - Four sites were devoted primarily to the production of nuclear fuels. Cleanup recently began at the Fernald environmental Management Project, where low-level waste, thorium compounds, and radium-bearing residues are undergoing remediation.
- Weapons Production and Testing Sites - Six DOE complexes handled nuclear weapons from the design and testing phases to the full production phase. These sites all have localized sub-surface contamination, and some have surface contamination with hazardous and mixed wastes related to drilling mud disposal pits.
- Physical Research - Sites devoted to basic research include Fermi National Accelerator Laboratory, Princeton Plasma Physics Laboratory, and Stanford Linear Accelerator Center.
- Waste Burial Sites - Major waste disposal locations include Hanford, Oak Ridge, Savannah River, Idaho National engineering Laboratory, Los Alamos National Laboratory, Fernald, and the Nevada Test Site. Smaller quantities of wastes are also buried at Ames Laboratory, Brookhaven National Laboratory, Sandia National Laboratory-Albuquerque, Lawrence Livermore National Laboratory, Paducah, and Portsmouth.
- Defense-Funded Environmental Restoration Projects - this program consists of 23 sites involved in the nuclear weapons program.
- Non-Defense-Funded Environmental Restoration Projects - Typically, these 22 sites were committed to the development of civilian nuclear power.

2. NRC Licensees

The NRC and its Agreement states currently license about 24,000 facilities for the production and handling of radioactive materials. About one third of these are NRC licensees, while the remainder are licensed by Agreement states under Section 274 of the AEA. Licensees include nuclear power plants, universities, medical institutions, radioactive source manufacturers, and companies that use radioisotopes for industrial purposes.

About 25 percent of NRC's 7,500 licensees use either only sealed radioactive sources or only small amounts of short-lived radioactive materials. Activities at facilities using only sealed sources are not likely to result in radioactive contamination that will need to be cleaned up, because the radionuclides generally remain encased unless the sealed source is broken open.

Overall, a small number of NRC licensees (e.g., radioactive source manufacturers, radiopharmaceutical producers, and radioactive ore processors) conduct operations that could result in substantial radioactive contamination in portions of the facility. In addition, about 250 facilities associated with the production of nuclear power maintain large inventories of radioactive materials, and many of these facilities may need to be cleaned up before the licenses can be terminated.

3. DOD Sites

The Department of Defense's Installation Restoration Program (IRP) consists of over 17,500 potential hazardous waste sites located at 1,877 installations. However, only a few of these sites are currently known to have radioactive contamination. DoD sites may contain small enclosed radiation sources, such as radium and tritium instruments, larger sources, such as research reactors contaminated with fission products, and dispersed sources, such as laboratory waste storage areas and test ranges contaminated with depleted uranium.

Most radioactive material handled at military sites results from research and development, testing of military munitions, and testing and operation of military reactors. The majority of radioactive waste is transferred to approved disposal sites and is not a threat to the local environment. However, both past and present DoD activities either generate or have the potential to generate radioactive waste. These practices include operation of nuclear reactors for energy production and research, maintenance of nuclear-powered ships, detonation of nuclear weapons and firing of depleted uranium shells at test sites, and storage of about seven million pounds of thorium nitrate and 16,000 tons of zirconium-bearing ore containing 0.3 to 0.4 percent uranium and thorium as part of the National Strategic Materials Stockpile.

4. CERCLA Sites

The cleanup standards may be applied to CERCLA sites contaminated with radioactive materials as an Applicable or Relevant and Appropriate Requirement (ARAR). Under the National Contingency Plan (NCP), EPA defines ARARs as either *applicable* requirements that address a hazardous substance, pollutant or contaminant, remedial action, or other circumstance at a Superfund site and that are enforced under existing law; or *relevant and appropriate* requirements which address situations sufficiently similar to those found at a contaminated site to be well-suited for site remediation. The substantive requirements of this rule would be expected to be an applicable requirement under CERCLA for those federal facility sites which are also considered applicable under this rule. The determination of whether these substantive requirements would be considered relevant and appropriate would require a comparison of eight site-specific factors.

C. MATERIALS COVERED IN THE PROPOSED RULE

Today's proposed rule sets standards for the cleanup and release of sites contaminated with radioactive materials. Radioactive materials generally are those materials containing radionuclides in concentrations that exceed typical natural background concentrations for their respective media. Radionuclides are those types of atoms which spontaneously undergo radioactive decay. This process of decay involves the spontaneous transformation of a radionuclide into one or more different radionuclides accompanied by either the emission of energy and/or particles from the nucleus, nuclear capture or ejection of orbital elements, or fission. Radionuclides may also decay into a more stable state, eventually reaching a non-radioactive isotopic form, or decaying into an interim radionuclide which is very long-lived. The type of radiation emitted by this decay process in a particular radionuclide depends upon the exact nature of the nuclear transformation, and may include emission of alpha particles, beta particles, gamma rays, neutrons or photons. It is these emissions that causes radiation exposure and damage to human health and the environment.

1. Human Health Effects

The level and type of hazard posed by radionuclides vary, depending on such characteristics as the radionuclide's radioactive half-life, the types of radiation it emits, the energy level of the emission(s), and its ability to concentrate in the body. Different radionuclides will irradiate different parts of the body causing different types of cancers.

There are three major types of long term health impacts from exposure to radiation: cancer, hereditary effects, and developmental effects on fetuses such as mental retardation. Since there is such a strong foundation for quantifying the risk of fatal cancer, EPA's consideration of fatal cancers is the principal health consideration in this rulemaking. Risk distribution of health effects from radiation calculated for most sources considered for regulation show that fatal cancers occur more frequently than non-fatal cancers and are substantially more significant than genetic or developmental effects.

Radiation is a demonstrated human carcinogen. No level of radiation exposure is expected to be risk-free. Health effects from radiation have been observed in studies of occupationally exposed workers, medically irradiated individuals, and survivors of the Hiroshima and Nagasaki atomic bombs. This information has been supported by studies of animals in laboratories. However, the effects of radiation doses at low levels of exposure can only be calculated by interpolating between the observed rates at higher doses and those at background levels since the increases at low exposure levels can not be directly observed. Some pollutants cause diseases that are unique to the pollutant; asbestos causes asbestosis. Radiation, however, causes the same types of cancers, e.g. leukemia and lung and liver cancer, that are caused by other factors. Since these cancers are not uniquely associated with radiation, it is not possible to differentiate cancers caused by radiation from other cancers.

The second type of effect is the induction of hereditary effects in descendants of exposed persons, which vary in degree and effect and may even be fatal. It is also assumed that there is no completely risk-free level of exposure for hereditary effects. Although hereditary effects have been observed in experimental animals at high doses, the expected rates in humans are too low to be observed.

Based on extensive scientific evidence, EPA believes it prudent to assume that carcinogens, including radionuclides, pose a risk of health effects even at low levels of exposure, i.e., there is no compelling evidence of a threshold. Based on this science policy judgement, EPA calculates health risk estimates assuming that the risk of incurring either cancer or hereditary effects at low levels of exposure is linearly proportional to the dose received in the relevant tissue. However, the severity of either effect is not related to the amount of dose received. That is, once an effect has been induced, its severity is independent of the dose.

Regarding cancer, there continues to be uncertainty on how best to interpolate between the absence of radiation effect at zero dose and the observed effects of radiation (mostly at high doses) in order to estimate the most probable effects at doses that represent small increases above natural background radiation. Taken together, however, current scientific data are generally indicative of risk per unit dose at low levels that is already a factor of 1 to 3 lower than those observed at higher levels.

2. Categories of Radioactive Materials

Radioactive materials can be grouped into five general categories:

- Source material,
- Special nuclear material,
- Byproduct material,
- Naturally-occurring or accelerator-produced radioactive material (NARM), and
- Naturally-occurring radioactive material (NORM).

The cleanup standards proposed today apply to all source material, special nuclear material, and byproduct material and to NARM and NORM at federal facilities and NRC licensees.

Authority for the radioactive material cleanup standard in today's proposal is drawn from the AEA and Reorganization Plan No. 3 of 1970. Source, special nuclear, and byproduct material are given special status under the AEA because they are uniquely associated with atomic energy production. Consequently, they are often referred to as AEA materials.

Source material is that which is essential to the production of spent nuclear materials and generally includes uranium and thorium or any combination of these materials or ores that contain 0.05 percent or more by weight of uranium or thorium. Source materials are primarily composed of unrefined and refined ores from which thorium, uranium, and other elements are extracted. Source materials also include purified materials or byproducts used or produced in the uranium enrichment and fuel fabrication process.

Special nuclear material includes plutonium and uranium enriched in the U-233 or U-235 isotope and any other material that the Department of Energy determines to be special nuclear material. Examples of these materials include enriched uranium at nuclear fuel fabrication plants, nuclear fuel at reactor sites, nuclear weapons components, and purified radiation sources used in research.

Byproduct material includes any radioactive material yielded in, or made radioactive by, exposure incident to the process of producing or utilizing special nuclear material and the tailings or wastes produced by the extraction of concentration of uranium and thorium from ore processed for its source material content. A wide range of radionuclides used for medical diagnosis and therapy, research, and commercial/industrial applications are derived from byproduct materials. These materials also include radionuclides found in uranium and thorium mill tailings and uranium and thorium series radionuclides.

Naturally-occurring radioactive material (NORM) is a subset of naturally occurring and accelerator-produced radioactive material (NARM). This larger category of NARM includes any nuclide that is radioactive in its natural physical state, excluding source, byproduct, and special nuclear material, and any radioactive material produced as a result of nuclear transformations in an accelerator.

NORM is specifically differentiated from NARM because it constitutes the cosmic and terrestrially-generated background radiation found on the earth. While NORM is found as a background radiation source, it can also be used as a source for industrial and commercial purposes. For example, radium sources are used for producing needles, gauges and dials, and NORM is found in the ores and large-volume wastes generated and managed at mining and mineral processing sites, coal and coal ash storage sites, and oil and gas exploration and production facilities.

The standards in today's proposal require cleanup to 15 mrem/yr above background radionuclide concentrations. Such background radiation is primarily caused by cosmic and terrestrial radiation sources of natural origin. As a result, although NORM is categorized as a radioactive material addressed by today's cleanup standard, naturally occurring radioactive material would be considered background radiation if it is present on a site as a primordial source. However, when the NORM becomes concentrated for production or as a waste material, and, as a result poses an excess cancer risk, it becomes subject to the cleanup standards in today's proposal that allow the release of federal facility sites.

D. SCOPE AND APPLICABILITY OF THIS PROPOSED RULE

Today's proposed rule stipulates cleanup and supplemental standards for the protection of human health and the environment from the multiple radiation exposure pathways found at radioactively contaminated sites. However, EPA acknowledges that somewhat different approaches for setting cleanup standards are appropriate for radioactive materials in ground water, in contrast to radioactive materials in soil and structures on the overall site. These approaches are addressed separately in the proposed rule and in the following discussion.

1. Overall Site

Today's proposed regulations establish radioactive material cleanup standards in the form of a dose limit applicable to an entire site, including soils, structures, surface water, and air. Cleanup standards for ground water are addressed separately. Site areas affected by this proposed rule are defined as those areas contained within the boundary of a location under the effective control of the implementing agency possessing or using radioactive materials or radioactive waste.

Under proposed 40 CFR part XXX, subpart A, contaminated sites are to be cleaned up in a manner that ensures that members of the public will not receive a dose in excess of 15 mrem/yr from radioactive materials remaining at the site after cleanup. This standard may be achieved either through cleanup of a site to ensure that an individual will not receive a dose in excess of 15 mrem/yr through all likely exposure pathways or through a combination of site cleanup and active control measures that will also limit individual exposures to less than 15 mrem/yr. Since EPA assumes a simple linear relationship between radiation dose and cancer risk, the proposed regulations are intended to limit the allowable exposure level for an individual, in terms of a lifetime cancer incidence risk, to 3×10^{-4}. By expressing the cleanup standard in terms of a dose limit, EPA is leaving the exact scope and nature of cleanup activities open to determination by site personnel and approval by regulators.

When determining likely exposure scenarios for a contaminated site, EPA distinguishes between on-site and off-site exposure pathways. In this way, greater certainty may be placed on developing cleanup activities that limit exposures to the public. For example, a site could be remediated for future use as a commercial or industrial facility. Therefore, exposures could be limited to the cleanup standard through a combination of cleanup activities and control measures limiting the amount of time individuals spend on-site working at the facility. In addition, the site would also need to be cleaned up to limit exposure to the radiation cleanup standard for individuals who live or work near the site year-round and for extended periods of time each day.

EPA is specifying that contaminated site owners and operators must clean up contaminated materials found at the site to achieve the cleanup standard. As a first priority, the owner or operator should ensure that the site is cleaned up to a level that will allow for unrestricted residential use of the site. If the site cannot be remediated for unrestricted residential use, the site owner or operator is required to propose an alternate site use and cleanup approach, which may include the use of active control measures to limit the amount of time individuals are exposed to the radioactive materials or the intensity of that exposure. Once the alternate site use, cleanup approach, or active control measures are identified, the site owner or operator must ensure that the cleanup is implemented and the site is maintained in a way that will limit the exposure of individuals located on-site and off-site to less than 15 mrem/yr for a period of at least 1,000 years.

By adopting this approach, EPA is not specifying the areas to be cleaned up, the technologies to be used, or the development and application of alternate site uses and active control measures. These decisions are left to the site owner and operator, with the oversight and approval of the appropriate regulatory agencies. In this way, EPA will ensure that a cleanup level is achieved that protects human health and the environment, but leaves sufficient discretion and flexibility in site cleanup decisions to promote equitable and cost effective cleanup activities.

2. Ground Water

Under subpart B of today's rule, EPA is proposing that remediation of sites shall be conducted so that radioactive material at the site shall not cause levels of radioactivity in any ground water that is a current or potential source of drinking water, in the accessible environment, to exceed the applicable Maximum Contaminant Levels (MCLs) for radionuclides established under the Safe Drinking Water Act (SDWA).

The ground-water cleanup standards require demonstrated compliance with the SDWA MCLs for radionuclides which are listed in 40 CFR part 141. The Agency is currently considering issuing revised MCLs which were proposed on July 18, 1991 (56 FR 33050). However, until that occurs, the Agency proposes to use the current levels, which were promulgated on July 9, 1976 (41 FR 28404). When MCLs for radionuclides are changed or added in the future, the Agency intends for those new MCLs to be the

ground water protection requirements used for the purposes of setting remedial objectives.

E. MEMORANDUM OF UNDERSTANDING

On March 16, 1992, EPA and the Nuclear Regulatory Commission (NRC) signed a Memorandum of Understanding (MOU) to "establish a basic framework within which EPA and NRC will endeavor to resolve issues of concern to both agencies that relate to the regulation of radionuclides in the environment." This MOU guides today's proposed EPA regulations and NRC's pending proposal to establish decommissioning standards. The MOU formally defined the roles, responsibilities, and separate rulemaking activities of each agency concerning regulations that affect NRC licensees and NRC-licensed facilities that manage radioactive materials.

Under the MOU, if EPA determines that NRC's regulatory program affords a sufficient level of protection to public health and the environment, EPA will propose in the Federal Register that NRC licensees be exempted from EPA radiation site cleanup regulations. This dual track approach provides the best means to help ensure that EPA cleanup regulations and NRC decommissioning standards are consistent and that goals of protecting human health and the environment are administered in an efficient manner.

F. RELATIONSHIP TO STATE RADIATION CLEANUP PROGRAMS

[To be added.]

III. STATUTORY AUTHORITY FOR PROPOSED REGULATORY APPROACH

[This section will be expanded and revised with OGC assistance.]

Under the Atomic Energy Act and Reorganization Plan No. 3 of 1970, EPA is authorized to develop federal guidance and to establish standards to protect health and the environment from the effects of radiation exposure. EPA is proposing today's rule pursuant to this AEA authority. The Safe Drinking Water Act (SDWA) provides additional support and authority for EPA's action, specifically with regard to the adoption of Maximum Contaminant Levels (MCLs) for radionuclides as standards for ground-water protection. In the following section, EPA cites the specific authorities supporting the development and implementation of radioactive material cleanup standards for contaminated sites and ground water.

A. OVERALL SITE RISK STANDARD

Under subpart A of today's proposal, EPA is establishing cleanup standards applicable to an entire contaminated site, including exposures derived from radioactive material in soils, structures, surface water, and air. EPA derives its authority to establish these cleanup standards from the AEA, as amended (42 U.S.C. § 2011 et seq.) and from Reorganization Plan No. 3 (35 FR 15623). The Plan provided EPA with the authority to establish "generally applicable environmental standards for the protection of the general environment from radioactive material." As stated in the Plan, "standards mean limits on radiation exposures or levels, or concentrations and/or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive materials." These generally applicable standards can include, among other things, limits on human exposure to radioactive material and cleanup levels for allowable concentrations or quantities of radioactively contaminated material in soil and other media.

The cleanup standards EPA is proposing today are expressed in terms of radiation dose limits to control the exposure of individuals located within or outside of contaminated sites. These standards govern exposure to radioactive materials at the site to less than 15 mrem/yr, above natural background radiation. The dose from these levels correspond to a lifetime cancer incidence risk of 3×10^{-4}. This limit is consistent with cleanup levels EPA has established under other authorities (see Section IV.A.1).

B. GROUND-WATER STANDARD

In addition to the AEA authority EPA is using to conduct this rulemaking and to set an overall radiation site cleanup standard, EPA derives authority under the Safe Drinking Water Act (SDWA) to set a supplemental cleanup standard for ground water. As noted previously, EPA is proposing that remediation of sites shall be conducted so that radioactive material at the site shall not cause levels of radioactivity in any ground water that is a current or potential source of drinking water, in the accessible environment, to exceed the applicable MCL for radionuclides established under the SDWA.

The SDWA provides authority for EPA's action as it reflects Congressional policies and purposes. The Congressional purposes that the SDWA advances are consistent with those underlying radioactively contaminated site cleanup programs. The SDWA was enacted to assure safe drinking water supplies. Pursuant to § 1412 of the SDWA, EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) for contaminants in drinking water which may cause an adverse effect on the health of persons and which are known or anticipated to occur in public water systems (40 CFR parts 141 and 142). These regulations specify either MCLs or treatment techniques and contain "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs (SDWA § 1401). The MCLs are the enforceable standards under the SDWA and represent the level of water quality that EPA believes is acceptable for consumption from public drinking water supplies. EPA is today proposing to adopt the MCLs for radionuclides, as standards for ground water protection under 40 CFR part 196.

Given the confluence of purpose of the AEA and the SDWA, subpart B is designed to provide an equivalent level of protection as would occur if the SDWA regulations for MCLs applied directly to ground water underlying a particular radioactively contaminated site. SDWA standards are applicable to drinking water that enters the home, not at the source of drinking water. However, the underlying requirement in the SDWA is that ground water, that is or can reasonably be expected to be a source of drinking water not adversely affect the health of persons when available for unrestricted use. In order to prevent adverse human health effects and allow unrestricted use of ground waters, SDWA standards must be applied to ground water aquifers that are current or potential sources of drinking water. This is accomplished by the requirement in subpart B that remediation of a radioactively contaminated site must ensure that radionuclide levels in such ground water will not exceed the applicable MCLs for 1,000 years.

C. PUBLIC PARTICIPATION

Today's proposal is based on the principle that communities must be involved in the cleanup process from the preliminary planning stages to the time the site is finally remediated. Communities near cleanup sites, including low-income, minority, and Indian communities, must be provided with the opportunity to fully participate in the cleanup process. In particular, the rule requires that the site owner/operator inform EPA of the intention to begin a cleanup action, notify affected state, local, and tribal governments, circulate public notice concerning the cleanup, establish a site-specific repository of information on the cleanup, and respond to public comments on the proposed cleanup.

These minimum standards are generally consistent with the minimum standards developed under other EPA remediation programs such as Superfund and RCRA.

EPA's proposal is based on the authority provided under the Atomic Energy Act (AEA) and the federal Administrative Procedures Act (the APA, 5 U.S.C. § 551 et seq.). The AEA authorizes EPA to establish generally applicable standards for the protection of the general environment from radioactive material. In addition EPA has broad authority to establish public participation requirements in order to carry out the purpose of the statute and to set out an orderly framework for implementation of the standards. In particular, EPA may include provisions regarding public participation as long as those provisions are reasonable, have a rational basis, and further the statutory goal. Although the AEA does not spell out specific public participation provisions that might be included in generally applicable environmental regulations promulgated under its authority, some guidance is provided by sections 2201(b) and 2201(p) of the AEA. These sections authorize EPA to establish regulations it "may deem necessary or desirable to . . . protect health or to minimize danger to life or property" and "as may be necessary to carry out the purposes" of the AEA, which encompass protection of the public health and safety.

Additional guidance is found in the provisions of 40 CFR Parts 190-192, which were promulgated under the authority of the AEA. Part 190 requires variance information to be made a matter of public record. Part 191 requires public notice and comment, opportunity for public hearings, and full consideration of public comments in selecting alternative provisions for disposal. Part 192, promulgated under the AEA as amended by the Uranium Mill Tailings Radiation Control Act, requires DOE to inform private owners and occupants of affected locations and to solicit their comments when remedial actions are proposed for a specific location.

The APA also provides statutory authority for the public participation provisions of today's proposal. Enacted in 1946, this statute was created both to standardize administrative procedures and provide a means of access to these procedures by citizens. Under the APA, federal agencies must provide the public an opportunity to participate in the decision-making process. Furthermore, the Act states that each agency must make available for copying and inspection all statements of policy and interpretations adopted by the agency that have not been published in the Federal Register, as well as administrative manuals and staff instructions that affect a member of the public. These requirements reflect fundamental Constitutional principles, including people's right to express their preferences with regard to decisions that affect their lives.

In addition, EPA believes that public participation may reduce the likelihood that cleanup decisions will be challenged in court. When lawsuits do occur, the courts frequently look to the records of public participation to determine if the Agency acted in a legal and responsible manner. The record of public participation can provide important support for the substance of a decision. It can also confirm that opportunities to participate were extended to the public and that public comments were considered.

EPA has been working with other federal agencies and the public to develop innovative methods for getting communities involved in the cleanup process. To this end, EPA has established the Federal Facilities Environmental Restoration Dialogue Committee (FFERDC), whose members represent 40 federal agencies, tribal and state governments and associations, and local, national, environmental, community, and labor organizations. The FFERDC's mission is to develop consensus policy recommendations aimed at improving the FFER decision-making process to ensure that cleanup decisions reflect the priorities and concerns of all stakeholders.

FFERDC recommends establishing site-specific advisory boards (SSABs) to help achieve:

- Consistent opportunities for affected stakeholder involvement in federal facility cleanups,
- Regular, early, and effective public participation in federal cleanup programs, and
- Consolidation of the many public involvement initiatives addressing cleanup.

Although EPA is not requiring the establishment of SSABs under today's proposal, EPA strongly encourages the use of SSABs (or similar mechanisms) and believes that they would promote early, direct, and meaningful participation through the cleanup process. Furthermore, the Agency believes that such participation is consistent with the goals of the AEA, APA, and other environmental statutes. Community groups could serve a central role in providing recommendations for land use restrictions or remediation techniques in the event that future land use is a factor in determining a cleanup action. Providing mechanisms for the active participation of community groups in selecting a remedial action might also be appropriate if such participation were necessary to the cleanup action. Finally, the President's Environmental Justice Executive Order 12898, signed February 11, 1994, encourages agency strategies, including rulemakings, that will ensure greater public participation. Under Executive Order 12866, agencies are encouraged to make the regulatory process more accessible and open to the public. Thus, meaningful public participation is a goal that is supported by and in keeping with the initiatives of the executive branch.

Section IV.D. of this Preamble summarizes the FFERDC's specific recommendations for SSABs and provides information on other effective procedures for involving the public in cleanup decisions.

IV. POLICY AND TECHNICAL RATIONALE FOR PROPOSED REGULATORY APPROACH

EPA is proposing a cleanup standard of 15 mrem/yr to guide cleanup activities at sites contaminated with radioactive material and to allow either unrestricted use of those sites or alternate uses coupled with active control measures following cleanup. This cleanup standard corresponds to an excess lifetime cancer incidence risk of 3×10^{-4}. EPA's derivation of this cleanup standard and lifetime cancer incidence risk level was based upon a detailed review of statutory authorities and precedents used in other programs. In addition, EPA also evaluated the assumptions and procedures involved in evaluating radiation exposure levels and human health risk at contaminated sites. The following section first provides the fundamental issues involved in evaluating the human health and environment caused by exposure to radioactive material. Section IV.A. then provides a detailed review of the critical findings and assumptions EPA developed in support of today's proposed cleanup standard and regulatory approach.

A. BASIS FOR PROPOSED RISK LEVEL

1. Background/Incremental Risk

The cleanup standards established in this proposed rule are intended to limit annual committed effective radiation exposures at a site to less than 15 mrem/yr above background radiation levels for at least 1,000 years following the completion of cleanup activities. EPA set the radioactive material cleanup standard to limit annual effective radiation exposures to an incremental level above background because of the extensive natural sources of radioactive materials already present in the environment, which provide the major source of human radiation exposure. This proposed rule focuses on exposures to human-generated concentrations of radioactive materials at sites that pose excess risk above levels that would normally be found in the environment.

General sources of natural background radiation and their average annual effective dose equivalents are cosmic (26 mrem), cosmogenic (1 mrem), terrestrial/soil (28 mrem),

inhaled radionuclides (200 mrem), and radionuclides in the body (39 mrem). The exposure of human beings to natural radiation arises from radionuclides that are present in the earth, or that have transferred from the earth to the atmosphere or hydrosphere, such as radon. The significant exposure comes from primordial radionuclides such as potassium-40, rubidium-87, and the radionuclides comprising the uranium-238, and thorium-232 decay series. The ultimate sources of these primordial radionuclides in the environment are the earth's crust and its underlying mantle.

The total concentration of major radionuclides of natural origin (potassium-40, rubidium-87, uranium-238, and thorium-232) in soil in the United States averages about 15 picocuries per gram (pCi/g). Radium-226 in soil averages at about 1 pCi/g, with a range of from .23 to 4.2 pCi/g. The resulting average gamma exposure to humans from soil is about 28 millirem (mrem) per year, excluding exposure to radon gas which is generated from the uranium. Assuming unrestricted residential use of a site, this dose is equivalent to a risk level of about 1.2×10^{-3} for a 70-year exposure or 5.3×10^{-4} for a 30-year exposure from these background sources in soil.

Typical concentrations of radium-226 in groundwater and surface water used as drinking water supplies range from 0.3 to 0.8 picocuries per liter (pCi/l), although concentrations as high as 200 pCi/l have been measured. Dissolved radon-222 concentrations in groundwater typically range from 50 to 300 pCi/l , although concentrations as high as 500,000 pCi/l have been measured. Surface water concentrations are generally below 10 pCi/l . The most common sources of these dissolved radionuclides are igneous rocks, sandstones, shales, and uranium-containing minerals.

By limiting exposure levels to 15 mrem/yr above natural background levels under this proposed rule, EPA is acknowledging that natural background concentrations of radionuclides vary among sites. As a result, radionuclide measurement methods must be adequate to distinguish contamination from natural background radiation levels. Where possible, the same measurement techniques should be used for the same radionuclide at both background and contaminated sites.

Although standard procedures for conducting site-specific background assessments are not yet developed, radioactive contamination can be measured independently of background radiation sources using generally available procedures. (Guidance which describes possible procedures for conducting site-specific background assessments is being developed in the "Site Investigation Manual," which is currently being developed by EPA in conjunction with DOE and NRC.)

2. Acceptable Level of Protectiveness

Under today's proposed cleanup standard, the extent of cleanup that must occur depends on the amount of remediation necessary to limit exposure to ionizing radiation to levels that pose an "acceptable level of risk." In order to determine the acceptable level of risk, EPA examined the risk levels that were considered protective in other governmental actions, particularly actions performed by EPA in other radiation-control programs. The Agency also reviewed the precedents set in regulations, guidances, and site-specific cleanup decisions. Based on these evaluations, EPA has identified an annual committed effective dose limit of 15 mrem/yr (0.015 mSv/yr) above natural background levels as the appropriate health-based cleanup standard for radioactively contaminated sites. This limit corresponds to a lifetime excess cancer incidence risk level of 3×10^{-4} (incremental risk above background).

The proposed cleanup standard is based on a variety of factors relating to protectiveness and consistency, which are discussed in the following sections.

- **i. Protectiveness**
  [Add discussion of precedents from 1992 H. Habicht memo. Add research from RIA concerning comparison of lives potentially lost to additional excavation/transportation vs. residual radiation left in place.]

  EPA has examined the issues of the protectiveness of various radiation levels on a number of occasions. EPA radiation protection regulations and guidelines have specified standards that correspond to risk limits in the range of 10^{-2} to 10^{-4}. For example, EPA's Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes ("High-Level Waste Rule," 40 CFR part 191) provides precedent for today's rulemaking. This rule sets a dose limit of 15 mrem/yr for all pathways and is designed to protect human health and the environment for 10,000 years. In the preamble to that rule, EPA stated that it finds that risk level acceptable because "it involves only a small number of people potentially being exposed to the maximum allowed individual risk."

  In addition, EPA set an effective dose equivalent of 10 mrem/yr for all radionuclide emissions under the National Emissions Standards for Hazardous Air Pollutants (NESHAPS, 40 CFR part 61). This dose corresponds to a lifetime excess cancer risk of approximately 2×10^{-4}. In the preamble, EPA stated that more stringent standards would produce only marginal risk reductions, although costs associated with those standards would have been high and may not have been feasible given the clean-up technology. This rulemaking included most pathways, but excluded ground waters.

  Standards issued under the Uranium Mill Tailings Radiation Control Act (UMTRCA), 40 CFR part 192, for cleanup of 23 uranium mill tailings sites, limit the concentration of radium-226, radium-228, and thorium at the surface to no more than 5 pCi/g over the background and limit the concentration of radium-226 below the surface to a screening level of 15 pCi/g over background.

  EPA's approach to radon has been non-regulatory, designed to provide public information and technical assistance to enable citizens to make informed decisions. The Agency has recommended an action level for radon of 4 pCi/l. Above the action level, EPA recommends the application of radon mitigation measures. EPA advises homeowners to consider mitigating homes that have radon levels above 2 pCi/l. The action level of 4 pCi/l corresponds to a lifetime (varies for smokers and non-smokers) cancer risk of 1.3×10^{-2} to members of the general population. In addition, EPA has published model standards to reduce radon in newly constructed homes. EPA based its recommendations on the application of best available technological controls taking costs into consideration.

  EPA has also developed a 25 mrem/yr standard for public protection from the activities associated with the uranium fuel cycle (e.g., nuclear power plants). Other attempts to deal with radiation protection have been summarized below.

  A standard of 15 mrem is generally consistent with these prior efforts. The radon standard was not developed on a strict health basis, but it took into account the feasibility of mitigation efforts in individual dwellings. The uranium fuel cycle, developed some years ago, took into account the benefits of the power generated. If the NESHAPs were to take into account the ground water pathway and were to use the 4 mrem limit that pertains to most radionuclides in water, it would closely approximate the 15 mrem standard chosen for the WIPP rule. The proposed 15 mrem standard is thus essentially consistent with both the NESHAPs and the very recent WIPP rulemakings. It offers greater protection than the Fuel Cycle Rule, and is a small fraction of the 100 mrem guidelines set for radiation exposures to the public from all sources.

A number of other considerations shaped our decision to propose a 15 mrem limit. These are discussed below. Although incremental increases in radionuclide contamination caused by human activity can be difficult to distinguish from natural background radiation levels, achieving a risk limit equivalent to 10^{-4} is technologically feasible and ensures a sufficient level of protection of human health. Establishing a limit lower than 10^{-4} may be technologically infeasible. For example, it is uncertain whether current techniques to measure soil and water contamination would be sufficiently sensitive to demonstrate compliance with a radiation risk limit below 10^{-4}. In particular, the measurement sensitivity of field hand-held instruments is limited compared to laboratory instrumentation. In addition, cleanup standards of much below 10^{-4} cannot be achieved at many DOE facilities because of a lack of technology appropriate for subsurface soil cleanup. [Expand on this point based on BID research to discuss specific technologies, e.g., excavation or vitrification.]

The incremental risk level of 10^{-4} above background allows for the recognition of naturally occurring background radiation and its inherent risk. In addition, the radionuclide cleanup level must be attainable and verifiable with available technology. The incremental risk level of 10^{-4} above background is feasible given current minimum detectable concentrations and cleanup technology.

- **ii. Precedent/Consistency**

In establishing the proposed risk level of 3×10^{-4} in today's proposal, EPA considered various risk levels applied by other statutory and regulatory actions, as well as those supported by nongovernmental bodies.

Consistency with Other EPA Regulations and Guidelines

Under the Safe Drinking Water Act, EPA sets Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs) for contaminants found in drinking water. MCLGs are set at concentration levels at which no known or anticipated health effects would occur. MCLs are enforceable standards which by statute must be set as close as possible to the health-based MCLG taking into consideration technical feasibility and cost. In the preamble to a recent proposed rule for radionuclide MCLs, the Agency stated that "longstanding and carefully considered EPA policy for regulating carcinogens in drinking water is that the lifetime individual risk target is one in 10,000 (10^{-4}) to one in 1,000,000 (10^{-6}) risk" (56 FR 33058).

As discussed above, Superfund's NCP has no specific standards for radionuclides or other contaminants. Rather, the NCP establishes nine criteria for remedy selection and determining cleanup levels; these criteria include the application of Applicable or Relevant and Appropriate Requirements (ARARs). In addition, cleanup levels are established on a site-by-site basis when they are not based on an ARAR, which is the case in about half of all Superfund cleanups. For these sites, 10^{-4} to 10^{-6} is generally considered the acceptable risk range.

EPA has examined the cleanup decisions made under Superfund to address sites contaminated with radioactive wastes. Many of these cleanup actions used the UMTRCA cleanup standard such as 40 CFR part 192 as an ARAR. Some of the sites used a State regulation as an ARAR.

For the majority of sites, an acceptable risk range of 10^{-2} to 10^{-4} was set. Since most sites used ARARs, the rationales for the risk levels were not discussed in the records of decision (RODs). One of the only remediation sites that did not use an ARAR was the Bomarc Missile Accident site, which was contaminated with plutonium. According to the ROD, no ARAR existed for plutonium. In this case, the Air Force "chose a very conservative course of action." The U.S. Air Force elected to clean up the site to a condition which would allow people to establish residence in the middle of the site for 70 years and not be affected. After discussions with EPA and New Jersey, the Air Force established a cleanup level based upon a 10^{-4} lifetime excess cancer risk. This involved excavation of soils with more than 8 pCi/g of plutonium.

Though standards for radionuclides are not specified within the RCRA Corrective Action standards (58 FR 8658), cleanup levels should be determined on a site-by-site basis, using other promulgated standards where appropriate. Generally, 10^{-4} to 10^{-6} is considered the acceptable risk range for all contaminants. Consistent with the NCP, RCRA Corrective Action regulations set an acceptable risk level of 10^{-4} to 10^{-6}. RCRA Corrective Action standards are designed to be consistent with Superfund. Cleanup levels are based on site-specific risk assessments.

Travis, et al. reviewed the risk levels found in federal regulatory decisions related to carcinogens and public health that were made between 1980 and 1985 to find guidance for setting an acceptably protective risk at hazardous waste sites. Quantifying the risk levels associated with 132 decisions, they determined 10^{-4} to be the *de facto* level of acceptable risk in a statistically significant number of federal regulatory decisions. However, cleanup levels that are based on an ARAR that is outside that risk range are generally considered protective.

Consistency with International and National Non-governmental Standards

International and national radiation protection guidelines developed by non-governmental bodies, such as the International Commission on Radiological Protection (ICRP) and the National Commission on Radiological Protection (NCRP), provide precedent for EPA radiation cleanup standards. These standards prescribe an annual committed effective dose limit of 100 mrem. This standard, like the standards specified in the Federal Radiation Protection Guidelines, applies to all radiation sources, except for background sources and medical procedures. EPA believes the proposed cleanup level of 15 mrem/yr represents an acceptable fraction of the 100 mrem/yr standard.

3. Alternative Risk Levels Considered

[To be added, this section will include: discussion on risk range, 50 and 70 year time frame, and dose limit options (10, 15, 25 mrem).]

4. Land Use

EPA recognizes that some sites it may not be appropriate to clean up to a level suitable for residential land use. In these cases, today's proposal provides that cleanup activities can be coupled with active control measures to allow for restricted use of these sites for residences or for commercial or industrial uses. This coupling of cleanup activities and control measures must ensure that members of the public do not receive doses over 15 mrem/yr in excess of natural background levels. Sites that are released

with active control measures to restrict land use, will still remain protective to members of the public

To provide guidance to facilitate the setting of cleanup levels, EPA will be providing radionuclide soil concentrations (RSCs) for sites where the intention is a release that is restricted to industrial/commercial uses. RSCs will be discussed in more detail in section IV.C.2. of this preamble.

- **i. Consistency with Other EPA Regulations**

  The use of active control measures during and after site cleanup as a means of achieving a clean-up standard is consistent with other relevant Agency regulations. For example, under the Comprehensive Emergency Response, Compensation, and Liability Act (CERCLA, or Superfund) future land use scenarios are considered in risk assessments to develop reasonable risk estimates for maximum exposed populations and to explore possible remedies. Remedy selection (and allowable future land uses) is a risk management decision that is made through evaluating criteria outlined in the NCP. In addition, under the administration's proposed "Superfund Reform Act of 1994," a reasonably expected future land use scenario is to be developed in cooperation with the public participation process as part of the remedy selection process.

  Institutional controls may be used at Superfund sites as interim measures or as part of a final remedy. When hazardous substances remain onsite and land or resource use is restricted, the site and remedy are revisited every five years to ensure protection of human health and the environment.

  Under RCRA, the owner or operator of a site must record a notation on the deed to the facility property-or on some other instrument that is normally examined during title search-which will in perpetuity notify any potential purchaser of the property of the site's former use and any relevant restrictions (40 CFR 264.119). Post-closure care for each hazardous waste management unit must continue for 30 years after certification of closure and must consist of at least monitoring and reporting, in addition to maintenance and monitoring of waste containment systems. (40 CFR 264.117, Post-Closure Care and Use of Property)

  EPA also has established similar provisions for high-level waste and uranium and mill tailings. EPA issued these rules under the authority of the Atomic Energy Act (AEA) and the Uranium Mill Tailings Radiation Control Act (UMTRCA), which allow EPA to establish generally applicable national standards.

- **ii. Purpose of Assurance requirement and Limitation if Active Control Measures Fail**

  Because control measures must be site-specific and frequently require ongoing maintenance and enforcement, EPA is proposing in today's action to require verification of the post-remedial dose every X years after remediation.

  In addition, EPA is proposing that in the absence of active or effective institutional controls, members of the public do not receive doses in excess of 75 mrem/yr in excess of natural background levels. In other words, members of the public would not receive doses in excess of this limit even if all of the controls at a site fail. While EPA fully expects implemented controls to be effective, this additional requirement provides assurance for cases where the effectiveness of active controls must be projected well into the future, which is of particular concern for this proposed rule because of the long-lived nature of many radionuclides.

  Although a committed effective dose of 75 mrem/yr corresponds to a lifetime excess cancer risk of 1.4×10^{-3}, this level is consistent with the ICRP recommendations of an overall dose limit from man-made radiation of less than 100 mrem. The 75 mrem/yr figure, accounts for the possibility that there might be another source of man-made radiation, in the vicinity of the site. EPA derived the 75 mrem figure by subtracting from 100 mrem, 25 mrem allowed by the Uranium Fuel Cycle rule, which is the highest dose allowed from a single source. EPA considered it extremely unlikely that there would be several sources of man-made radiation within the vicinity of a single site.

  Also, EPA did not want to choose a number that was so low that it would in effect require a site to either be cleaned up to a level that allowed it be released for residential use or not to be released at all. This may occur because permitting a site to be released for industrial/commercial use allows the implementing agency to leave a higher radionuclide concentration than if the site were to be released for residential use. This is because an industrial/commercial exposure scenario generally has fewer exposure pathways than a residential scenario. The 75 mrem/yr dose has been chosen as an appropriate balance between protecting the public should institutional controls fail, and imposing additional standards in those cases when institutional controls have been determined to be appropriate at a given site.

5. Time Frame

Several critical time frame issues are involved in determining and complying with the cleanup standard dose limit of 15 mrem/yr. This standard is intended to limit the lifetime excess probability of cancer incidence for an exposed individual to 3×10^{-4}. The determination of this risk of cancer incidence is based upon an estimated lifetime exposure of 30 years for individuals located on or near the contaminated sites. In addition, EPA stipulates that compliance with these standards is to be achieved over a period of at least 1,000 years. The following section discusses the rationale for these time frame issues.

- **i. Lifetime Exposure Scenario**

  In developing the 30-year lifetime exposure scenario, EPA evaluated the risk assessment exposure assumptions currently being used to assess chemical and radiation hazards, both by other EPA programs and by other federal and international agencies involved in radiation risk management. EPA determined that the scenarios used by these other agencies generally assume that lifetime exposures occur over either a 30- or a 70-year period, with one recent rulemaking, the "Environmental Radiation Protection Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes" using 50 years as the lifetime exposure period (58 FR 66416, December 20, 1993).

  Although precedents exist for both 30-year and 70-year lifetime exposure scenarios, EPA chose to use the most recent, generally applicable risk assessment guidance available under the CERCLA program to support the risk assessment approach adopted under this rulemaking. The Superfund recommendation of a lifetime exposure period of 30 years is the most recent assessment of the exposure time period issue, although the 30-year assumption is not used by all Agency programs. It also is the most similar source of information for application to site cleanup efforts. EPA believes it is important that today's proposed rule be consistent with the Superfund recommended exposure period of 30 years since many of the radiation contaminated sites are identified under CERCLA authority. Superfund states that the 30-year assumption represents the national upper-bound time (90th percentile) at one residence (EPA, 1989a). Superfund obtained the 30-year assumption from EPA's Office of Research and Development "Exposure Factors Handbook" which is based on a 1983 survey by the Bureau of the

Census.

The Superfund Risk Assessment Guidance, Human Health Evaluation Manual (EPA, 1989a) recommends using the following assumptions when calculating exposures to an RME individual:

- Members of the general population are exposed for 350 days per year for 30 years.
- This assumption is used to evaluate future residential, agricultural, and recreational land use scenarios for contaminated sites.

Workers are exposed for 250 days per year for 25 years. This assumption is used when evaluating future industrial/commercial land use scenarios.

- **ii. Intergenerational Time Frame Issues**

The second time frame issue considered under today's proposed rulemaking concerns the period of time over which achievement of the cleanup standard must be reasonably assured. EPA is proposing that contaminated sites must be cleaned up in a manner that provides a reasonable expectation that, for 1,000 years after completion of the remedial action, radionuclide concentrations in excess of natural background levels must not exceed amounts that would cause any member of the public to receive, through all potential pathways, an annual committed effective dose in excess of 15 mrem/yr. In the absence of active control measures, the same dose limit applies and the annual committed effective dose must not exceed 15 mrem/yr.

One of the principal issues involved in assessing this 1,000 year period of compliance, which is referred to as an intergenerational time frame, concerns very long-lived radionuclides. Such consideration is necessary to account for the risks posed by residual levels of long-lived radionuclides, and the growth of their decay products. More than two dozen radionuclides are believed to contaminate sites requiring cleanup under today's proposed rulemaking. The radionuclides' half-lives range from less than 1 year to more than 4.5 billion years. Furthermore, the decay products from many of these radionuclides may also pose high radiation dose risks. It should be recognized that the activity of individual radionuclides and radioactive decay series (radionuclides with a series of decay products) and the associated hazard does decrease with time. The table below gives the half-lives of selected radioisotopes of concern.

Because of these extended half-lives, EPA determined that site cleanup activities should ensure maintenance of the cleanup standards across multiple generations. Although the Superfund Human Health Evaluation Manual does not provide explicit guidance on the appropriate time frame over which to assess radiation risks at a site, it does note that consideration of multigenerational effects is useful when assessing the risks posed by long-lived radionuclides.

Half Lives of Selected Radionuclides of Concern

Radioisotope	Name	Half Life[a]	Radioisotope	Name	Half Life[a]
Am-241	Americium	458 years	Pu-239	Plutonium	2.44×10^4 years
Co-60	Cobalt	5.26 years	Pu-240	Plutonium	6,580 years
Cs-137	Cesium	30 years	Sr-90	Strontium	28 years
H-3	Tritium	12.3 years	Tc-99	Technetium	2.1×10^5 years[d]
I-129	Iodine	1.7×10^7 years	Th-230	Thorium	8.0×10^4 years
Np-237	Neptunium	2.14×10^6 years[c]	U-235	Uranium	7.1×10^8 years
Pu-238	Plutonium	87 years	U-238	Uranium	4.51×10^9 years

[a]Source unless otherwise noted: USEPA. 1992. *Guidance for Data Useability in Risk Assessment (Part B). Final.* OSWER 9285.7-09B. [b]Source: CRC 1964. *Handbook of Chemistry and Physics. 46th Edition.* Cleveland, OH: The Chemical Rubber Company. [c]Source: USEPA. 1989a. *Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual (Part A).* EPA 540/1-89-002. [d]Source: USEPA. 1993a. *Background Information Document for Radiation Site Cleanup Regulations. Interim Draft Number 1.* December 15, 1993.

Several other EPA regulatory programs have also reviewed this issue. EPA's high-level waste (HLW) disposal regulations, 40 CFR part 191 (1985), are designed to protect human health and the environment for 10,000 years. The proposed low-level waste disposal rule (LLW), (1989) 40 CFR parts 193 and 764, assesses health in the population for 1,000 to 10,000 years, with the 1,000-year time frame addressing impacts to local population and critical population groups, and the 10,000-year time frame addressing impacts to a regional population. The Uranium Mill Tailings Standards (under the Uranium Mill Tailings Radiation Control Act), (1983) 40 CFR part 192, assess population doses over 1,000 to 10,000 years.

Several other EPA programs evaluate intergenerational exposures over shorter time periods. The National Emissions Standards for Hazardous Air Pollutants (NESHAPs), (1989) 40 CFR part 61, subparts H and I, include an assessment of the population effects caused by accumulation of radionuclides in the environment over a 100-year period. Fuel Cycle Standards, 40 CFR part 190 (1976), assess population dose based on an accumulation of radionuclides in the environment over a 100-year period for ^{85}Kr, ^{129}I, ^{239}Pu, and other alpha-emitting transuranic radionuclides.

In evaluating these latter precedents, EPA determined that the 100-year time frame is customarily used to be consistent with the typical expected life of an operating facility. However, after the facility is closed, much of the radioactive material is either removed or readily decays from the sites typically addressed under the NESHAPS or fuel cycle standards. This consideration is in many respects directly applicable to the characteristics of many of the contaminated sites addressed by today's proposed rule. Although some long-lived radioactive materials may remain on these sites as part of the cleanup and disposal process, for most radionuclides of interest at sites the peak dose occurs in less than 1,000 years. Therefore, EPA proposes to require that annual committed effective dose equivalent estimates be based on the greatest annual dose expected within the first 1,000 years after site remediation.

For sites at which residual radioactive materials will remain after cleanup, a period of 1,000 years is recognized by the Agency as being long enough to identify health impacts. In contrast, EPA concluded that the 10,000 year time frame used to evaluate the high-level waste rule is of sufficient duration to model the long-term performance of disposal systems. The rationale supporting the draft low-level rule also notes that a disposal modeling period of 1,000 to 10,000 years is necessary since several radionuclides are hazardous for this period, and some disposal methods will prevent radionuclides from reaching an exposed population for a long time. Disposal of radioactive waste requires by necessity the permanent isolation of potentially harmful material from the accessible environment. By contrast, cleanup implies removal of these harmful materials for disposal elsewhere. Thus, the intrinsic nature of these two activities are distinctively different. This difference supports the use of the 1,000 time frame in the case of cleanup, thereby reducing implementation burden and modeling uncertainty.

When predicting thousands of years into the future, uncertainties become very large because of major potential changes in the geohydrologic regime at the site over long periods of time. When the potential consequences of exposure to the radioactive source are great, as in the case of a high-level waste repository, distant future calculations may provide some insight concerning the relative magnitude of consequences. However, the consequences of exposure to residual radioactivity at levels approaching background are small, and considering the large uncertainties, long term modeling of near background doses may be virtually meaningless. In light of this, EPA does not believe it would serve any purpose to attempt to estimate radiation doses from residual radioactivity greater than a thousand years into the future.

In sum, EPA is proposing an intergenerational time frame of 1,000 years as the assessment period for cleanup activities to ensure that the creation of decay products and the long-term integrity of active control measures is adequately considered. Furthermore, the 30-year lifetime exposure scenario is consistent with current EPA and risk assessment procedures followed for CERCLA cleanups or removal actions.

6. Measurement

Radionuclide concentration levels and associated risk levels that can be quantified vary depending on the radionuclide of interest. Eight radionuclides identified by EPA may be difficult to detect at a risk level of 1×10^{-4}, considering MDCs generally achievable by commercial laboratories, soils contamination, and residential exposure scenarios. In addition, nineteen radionuclides would be difficult to detect in soils at concentrations equivalent to a risk level of 10^{-5}. About 30 radionuclides would be difficult to detect in soils at concentrations equivalent to a risk level of 10^{-6}.

In actual measurement situations anticipated for sites affected by today's proposed rule, a combination of field survey techniques and laboratory measurements may provide the most efficient means of measuring levels of radioactive materials. As discussed above, exclusive reliance on either field survey techniques or laboratory measurements may not always be advisable. Instead, field survey measurement techniques can be used to focus and economize on laboratory measurements.

In general, EPA concludes that sufficient field or laboratory radionuclide measurement techniques are available to support implementation of today's proposed rule at the proposed risk level. At levels below that proposed, measurement issues become increasingly difficult to overcome.

7. Population and Individual Risk

The cleanup standard EPA is proposing is intended to protect the reasonably maximally exposed individual (RME) in the population located on or near a contaminated site. The RME is defined as the individual receiving the radiation exposure experienced by the 95th percentile and above of the population near a site (i.e., the upper five percent exposure level for individuals at the site). When calculating the RME exposure level, EPA assumes that everyone living or working near a site is exposed to radioactive materials through multiple exposure pathways, such as external radiation from photon-emitting radionuclides in soil, inhalation of resuspended soil and dust containing radionuclides, incidental ingestion of soil containing radionuclides, or ingestion of drinking water containing radionuclides transported from soil to potable groundwater sources.

As a result, the RME exposure accounts for multiple radioactive material sources. By protecting this upper-bound individual exposure, EPA believes that the majority of individuals at a site are protected.

EPA also evaluated the use of a population risk estimate as the basis for the cleanup standard. Population risk refers to an estimate of the extent of harm for the population or population segment being addressed. Population risk is often expressed as the number of health effect cases (e.g., cancer cases) in the population of interest over a specified period of time. EPA typically uses estimates of population risk to look at the costs and benefits of a specific regulation. For example, the regulatory impact analysis for today's rule assesses the number of cancer cases averted through application of the cleanup standard and the associated costs. When setting radionuclide and chemical carcinogen standards, however, EPA generally considers individual risks (e.g., to the RME).

EPA is using the RME as the basis for today's proposed risk standard in order to be consistent with EPA policy and recent risk assessment guidance. [Add discussion of 1992 H. Habicht memo.] For example, the National Oil and Hazardous Substance Contingency Plan for Superfund Remediation (40 CFR 300) outlines procedures for assessing risk to the RME at hazardous waste sites. The risk range to be achieved under CERCLA site clean ups of 10^{-4} to 10^{-6} is also defined for controlling exposures to the RME.

Limiting the RME to a specified risk and considering population risk in support of cost/benefit analyses is protective of human health and is consistent with the general approach of other EPA programs, including radioactive material management programs. Furthermore, assessing the reasonable maximally exposed (RME) individual is consistent with Superfund guidance [Add stronger rationale for consistency with Superfund]. The reasonably maximum exposed (RME) risk measure estimates a conservative exposure case that is well above the average case but is still within the range of possible exposures. [Discuss how this compares with the "usual" radiation regulatory or guidance analysis.]

8. Cost

[This section will be developed when the cost analysis portion of the RIA is completed.]

9. Worker Health and Safety

[This section will be expanded when the worker health and safety analysis portion of the RIA is completed.]

Like regulatory costs, impacts of the proposed regulation on worker health and safety include the incremental impacts above those that would have been incurred in the absence of the proposed standard. Worker health and safety impacts arise from radioactive and non-radioactive sources. The radioactive sources of worker impacts are caused by changing the period of exposure to the radioactive wastes relative to what they would have been in the absence of the proposed standard. The non-radioactive sources include onsite industrial accidents and traffic accidents caused by transportation of the waste to off-site disposal facilities.

The estimated radiation-related worker impacts reflect the difference in the number of person-hours of exposure associated with remediating a site to meet the proposed standard relative to the cleanup level that would have been achieved otherwise. In calculating the non-radiation-related worker impacts, EPA estimated the number of industrial and traffic accidents associated with the different level of remediation effort necessary to achieve the proposed standard.

The proposed standard would cause an estimated [increase/decrease] in both fatal and non-fatal worker incidents. As with the estimated regulatory costs, the individual impacts appear to be highly site-specific. The major determinants appear to be the activity level of the radionuclide contaminants, the total volume of contamination, and the baseline cleanup level that would have been achieved in the absence of the proposed standard.

10. Ecological Effects

The cleanup standard EPA is proposing is intended to limit excess cancer incidence in humans to 3×10^{-4}. Although EPA set this standard at a level designed to protect human health, this standard is also protective to many ecological receptors. EPA intends that today's proposed standards be sufficiently protective of ecological receptors. However, difficulties inherent in assessing radiation exposure levels to ecological receptors, such as fish, wildlife, and plants, and limitations in the understanding of radiation dose-response relationships for many of these receptors make the prediction of ecological effects at contaminated sites problematic. Nonetheless, several conclusions can be drawn from the existing literature concerning the effects of radiation on ecological receptors.

Chronic Exposures

One important aspect of examining ecological effects is chronic exposure. Impacts from chronic exposure to radiation typically vary with the level of cellular organization in the receiving plant or animal. Impacts at the molecular level usually require greater than 10,000 rad. At the cellular level, radiosensitivities vary, with immature, rapidly dividing cells being most sensitive and non-dividing and fully differentiated cells least sensitive. There is a tremendous range of sensitivity to chronic radiation doses among species. With regard to plant communities, early successional stage communities tend to be more resistant that later ones, and vascular plants are more sensitive than thallophytes. Reproduction and growth can be reduced at reasonably low exposures. At higher exposures, breakdown of community structure can be expected. Radiosensitivities of food crops varied with winter barley being most sensitive and showing responses similar to winter wheat. A comprehensive review of plant sensitivities indicated that radiosensitivities for plant communities with trees being most sensitive and sensitivities for shrubs, herbs, thallophytes, and microflora ranging from most to least. Old-field diversity was severely reduced at a chronic exposure rate of approximately 1000 rad/day. An oak-pine forest had similarly reduced diversity, but at a much lower chronic exposure rate of approximately 100 rad/day.

EPA found that, in general, knowledge of radiation effects from chronic exposures to animal populations in irradiated ecosystems is more limited than on plant populations and communities. The process most susceptible to impairment in animals is reproduction. The biotic and abiotic environment, as well as many other innate characteristics, can significantly alter the response of animal populations to radiation. As a result, the prediction of population response in irradiated ecosystems is difficult, unless the exposures are either very low or very high. Mammals such as burros (LD_{50} = 255 rad), cattle (LD_{50} = 125 to 160 rad), dogs (LD_{50} = 250 rad), goats (LD_{50} = 240 rad), and swine (LD_{50} = 250 rad) are more radiosensitive than humans (LD_{50} = 300 rad) at acute exposure levels, and because of their slow recovery rates may tend to be even more sensitive to chronic exposure. Mice irradiated *in utero* at a dose of 1.2 rad/day had lower birth rates, higher death rates, and age-specific fertility was reduced, while no effects were apparent for mice irradiated since weaning.

EPA also found that studies on natural aquatic populations have been limited to systems contaminated with radionuclides to produce dose rates less than 1 rad/day. At such levels, the responses of aquatic populations to radiation have been very difficult to document and quantify. A 1993 review indicates that reproductive and early developmental stages in aquatic organisms are most sensitive to chronic radiation. Studies of chinook salmon embryos irradiated with low doses (<1 rad/day) until release as smolts showed no excess mortality, increased number of viable eggs, and increased return of spawning females. At greater doses $>$ 9.5 rad/day there were fewer returning spawning adults.

Acute Exposures

Another important aspect of examining ecological effects is acute exposures. The range of responses to acute or high-level radiation doses also varies with species type. Virtually all organisms require an acute dose of greater than 100 rad before significant mortality can be expected. Effects on reproduction or growth can occur at 10 percent to 1 percent of the lethal dose. Very low doses of less than one percent of the lethal dose, are not likely to produce measurable perturbations in populations or communities.

Invertebrates tend to be less sensitive than vertebrates, and juveniles are generally more sensitive than adults because juvenile forms have more dividing cells. Within invertebrate species, males are often more sensitive than females. Ranges of acute LD_{50}s for radiation exposure to invertebrates vary: crustaceans (1,500-57,000 rad), mollusks (20,000-109,000 rad), and echinoderms (20,000-200,000 rad).

Responses to radiation exposure in fish populations also varies with early life stages being more sensitive than older life stages. Doses greater than 1000 rad can cause irreversible damage to reproductive tissue resulting in permanent sterility in fish. Data on effects in amphibians and reptiles are more limited; however, amphibians also exhibit differences in life stage sensitivity. Accumulation of approximately 1500 rad was sufficient to destroy the ovaries of some female lizard species.

In birds, tissue radionuclide concentrations were found to be representative of the feeding habits of feral populations, with higher concentrations of radionuclides in insectivorous bird and lower concentrations in piscivorous birds. In other studies, effects were observed on breeding plumage, testes, feather growth, nesting ability, bone marrow, spleen, and duodenum, and other internal organs. Acute LD_{50} values for feral birds ranges from 400 to greater than 1000 rad.

There is a larger volume of literature on the effects of acute radiation on plants, as compared to information for animal species. Usually, the larger the plant species, the more sensitive it is to irradiation. Woody plants tend to be about twice as

sensitive as herbaceous plants, and conifers are some of the most radiosensitive plant species.

Based on these analyses, EPA concluded that the proposed cleanup standard will be sufficiently protective of many ecological receptors. This finding is based on the general conclusion that:

- Invertebrates, non-vascular plants, and reptiles and amphibians are highly resistant to radiation effect compared to mammals such as humans.
- Several species of large mammals such as the donkey, cow, dog, sheep, and swine appear to be equally sensitive as humans to acute radiation exposure.
- Certain pines and some wild birds are as radiosensitive as many mammals following chronic radiation exposures.
- Birds are generally less radiosensitive than most mammals.
- Aquatic vertebrates are considerably more radio-sensitive than invertebrates and exhibit sensitivities similar to that of terrestrial mammals.

This information suggests that the cleanup levels established in today's rule would also be protective for many fish, plants, and wildlife.
[Add discussion of radionuclide chemical toxicity.]

B. RATIONALE FOR FORM OF STANDARD

EPA is providing in this section IV.B. of the preamble, the rationale for the form in which the standard was developed. This section focuses on the dose limit that was selected to address the overall risk posed by a site; the inclusion of separate ground water requirements in addition to overall site risk standard, and; the requirement to comply with indoor radon guidelines. This section also includes a discussion of which other options were considered but not selected as the preferred option for this proposed rulemaking.

1. Rationale for Overall Site Risk Standard

- **i. Rationale**

EPA is proposing in § 196.04 that for a site to be released, the level of radionuclides ensures that members of the public are limited to 15 mrem/yr, employing exposure assumptions appropriate for the selected land use scenario (e.g., residential or industrial/commercial).

By applying today's cleanup standard as an overall site dose limit, EPA will provide for protection of members of the public from all relevant exposure pathways at a site without predetermining an approach for summing the additive risks. Instead, site owners and operators will be directed to account for all likely exposure pathways and to devise remediation approaches that will limit members of the public to a total dose of less than 15 mrem/yr. Thus, when a site is remediated, one must determine what potential exposure pathways exist and what levels of risk they pose. Potential pathways include soil, water, air, and contaminated structures at a site.

Under the proposed regulations, risk is treated as additive for each of the exposure pathways. In other words, the total risk presented by a site is the sum of the risks of each exposure pathway. Therefore, all likely exposure pathways must be considered to determine if a site meets a particular risk level above background. This principle implies that risks from exposure to contaminated soil and air are additive to the extent that people using the site after cleanup face both exposure pathways. EPA believes this is an appropriate approach because it allows considerable flexibility in determining the best approach for remediating each site.

- **ii. Other Overall Site Risk Standard Approaches Considered**

EPA reviewed several alternative approaches to today's proposed overall site risk standard. The approaches EPA considered but did not select as the preferred option, include:

- a pathway by pathway dose limitation.
- technology-based requirements.
- a "lookup" table of radionuclide and medium-specific cleanup standards for a site; and
- a "lookup" table combined with a pathways model to establish site-specific cleanup standards; and

EPA's rationale for not selecting as the preferred approach each of these alternative approaches is as follows.

Pathway by pathway dose limitation

[to be added later]

Technology-Based Approach

EPA did not select this alternative because this approach would not allow cleanup actions to be tailored to site-specific conditions, which would reduce the involvement of the public in the site cleanup process, and which could also result in less efficient cleanups with no improvement to the environment. This approach would require the Agency to undertake an enormous amount of analysis and study to determine an appropriate range of technologies, given the wide variation in the types of radiation contamination problems. The Agency also would have to decide how the regulations would accommodate future advances in technology. It would require EPA to spend considerable effort keeping of technological advances and keeping the regulations up to date.

Lookup Table and Lookup Table Combined with a Pathway Model

EPA did not select the Lookup Table approach as part of the rule's proposed requirements because of the difficulty in selecting appropriate exposure scenarios and models to derive radionuclide concentrations. EPA also did not select the Lookup Table Combined with a Pathway Model approach as part of the rule's proposed requirements because the Agency concluded that this approach would be more difficult to develop than would a dose or risk limit or a table of radionuclide concentrations alone. However, as discussed further in section IV.C. of this preamble, EPA will be providing RSCs as a guidance form of lookup tables in the BID for this proposed rulemaking. EPA believes that these will, in most site situations, provide guidance to facilitate the setting of cleanup levels.

2. Ground Water

- i. Rationale

The EPA is proposing separate ground water protection requirements in Subpart B because ground water is unique and deserving of pollution controls separate from other environmental media. Ground water contamination is of particular concern to the Agency because of its potential impact on sources of drinking water. Over 50 percent of the U.S. population draws upon ground water for its potable water supply. Approximately 117 million people in the U.S. get their drinking water from ground water supplied by 48,000 community public water systems and approximately 12 million individual wells. The remaining people get their drinking water from 11,000 public water systems drawing from surface-water sources. About 95 percent of rural households depend upon ground water, as does a still larger proportion (97 percent) of the 165,000 non-community public water supplies (such as those for camps or restaurants serving a transient population). Thirty-four of the 100 largest U.S. cities rely completely or partially on ground water. In addition, ground water contamination is of concern to EPA because of its potential impact upon the ecosystem.

Since ground water is not directly accessible, its contamination is far more difficult to monitor and/or clean-up than is contamination in other environmental media. Agency analyses of CERCLA sites indicated that, of all the potential environmental pathways, ground water is the most likely pathway media to be adversely impacted at these hazardous waste sites. In addition, ground water generally moves slowly; velocities are usually in the range of 5 to 50 feet per year. Large amounts of a contaminant can enter an aquifer and remain undetected until a water well or surface-water body is affected. Moreover, contaminants in ground water, unlike those in other environmental media like air or surface water, generally move with relatively little mixing or dispersion, so concentrations can remain high. These plumes of relatively concentrated contaminants move slowly through aquifers and may be present for many years, sometimes for decades or longer, potentially making the resource unusable for extended periods of time. Because an individual plume may underlie only a very small part of the land surface, it can be difficult to detect by aquifer wide or regional monitoring. Slow migration over thousands of years, can cause a large area to become contaminated and will increase the potential for exposure to those contaminants. All of which favor effective restoration of contaminated ground water, and remediation of radioactive materials in other media (e.g., soil) to the extent that future contamination of ground water may be prevented.

The Agency believes it is prudent to restore contaminated ground water whenever technically practicable, and to

protect ground water resources from contamination through remediation of other media to radiation levels that ensure contaminant levels in ground water will not exceed MCLs. This approach avoids requiring present or future community water suppliers to implement expensive clean-up or treatment procedures and protects individual users, as well. Moreover, remediation of contamination in other media, which could otherwise cause future ground water contamination will prevent expensive clean-up by future generations.

Today's subpart B standards are consistent with the 1987 First Circuit ruling, since the standard pertains to ground water that is a current or potential source of drinking water located outside the controlled area surrounding radioactively contaminated sites. See *Natural Resources Defence Council* v. *EPA*, 824 F.2d at 1274.

This approach is consistent with the Agency's overall approach to ground water protection, that is, to restore to MCL levels contaminated ground water that is a current or potential source of drinking water, and to prevent the contamination of current and potential sources of drinking water. This approach is reflected in Agency regulations pertaining to hazardous waste cleanup at sites (40 CFR 300) and facilities (40 CFR 264). The Agency's analyses demonstrate that these objectives are scientifically and technically achievable assuming well-selected and well-designed remedial actions.

Subpart B protects ground water that is a current or potential source of drinking water in the vicinity of radioactively contaminated sites by requiring that the remedial actions be designed so as to assure that ground water will not be contaminated above the MCLs. In other words, before the remedial action is considered completed, the implementing agency must determine, considering the uncertainties in the analysis, that the undisturbed performance of the remedial action, over a 1,000-year period, will not cause releases which could result in the radionuclide MCLs being exceeded in ground water underlying the site.

- **ii. Other Ground Water Approaches Considered**

In developing the approach to ground water protection contained in today's proposal, EPA also considered two alternative approaches involving (1) addressing ground water only as part of the overall site protection standard established under subpart A of the rule, or (2) using AEA-specific cleanup standards, rather than MCLs. EPA did not select these alternative approaches for the following reasons.
[To be added]

3. Indoor Radon

EPA is proposing in § 196.04(d) that on a remediated site all new and existing structures, such as homes or commercial buildings, must meet the indoor radon guidelines of EPA's radon program. Through this nonregulatory program, EPA recommends that all homeowners apply mitigation procedures if levels of radon-222 exceed 4 picocuries per liter (pCi/L) of air. Under today's proposed regulation, structures on remediated sites would be required to comply with this standard as well as any other applicable federal, state, or local government radon regulations and/or guidance.

EPA believes this is an appropriate approach because it allows site-specific flexibility in determining how to meet the radon standard and at the same time ensures that the hazards presented by indoor radon are minimized.

Soil concentrations of radium-226 above background levels that remain after remediation of sites contaminated with uranium-238 or radium-226 could lead to concentrations of indoor radon gas above background levels in structures remaining at a site or in structures built on a site following remediation. Both radionuclides are found in various concentrations in most soils and rocks. The decay of radium-226 (a "daughter" of naturally-occurring uranium-238) results in the formation of radon-222, a radioactive gas. Radon inhalation, primarily as an indoor air problem, may be the second leading cause of lung cancer in the U.S., resulting in 7,000 to 30,000 deaths each year.

Based on the application of available technological controls, EPA has recommended a 4 pCi/l "action level" for radon-222 and advises consideration of mitigation for levels above 2 pCi/l. In choosing action levels, the limitations of technology were important. It is cost-effective to set the action level lower than 4 pCi/l, but not consistently attainable or measurable with current technology. EPA has recommended this level through a nonregulatory approach under the authority of the Indoor Radon Abatement Act (IRAA), which directed EPA to undertake a variety of activities to address the growing public concern over dangers posed by exposure to indoor radon. The law directed EPA to study radon levels, evaluate mitigation methods, establish proficiency programs, assist states with program development, develop training centers, and provide public information. In choosing action levels, the limitations of technology were important. It is cost-effective to set action levels

lower than 4 pCi/l, but these lower levels would not be consistently attainable or measurable with current technology.

The recommended 4 pCi/l action level corresponds to an individual lifetime cancer risk (ILCR) of about 1.3×10^{-2} to the general population. Since the risk of lung cancer from radon exposure appears to be enhanced by cigarette smoking , EPA estimates that the ILCR varies from 1.55×10^{-3} for never smokers to 2.9×10^{-2} for smokers exposed to 4 pCi/l over a lifetime. It is possible that some sites may comply with the cleanup standard (i.e., about a 10^{-4} ILCR above natural background radiation risk), and have an indoor concentration of radon-222 greater than 4 pCi/l. This situation could occur because of a variety of factors: 1) in some regions of the country, indoor concentrations of radon-222 from natural background sources are above or slightly below EPA's 4 pCi/l recommended action level; 2) the site cleanup standard specifies a cancer risk level above natural background radiation; and 3) EPA's recommended action level for radon-222 of 4 pCi/l is an absolute measure of indoor concentration including contributions from natural background radiation. Therefore, it is possible that even a small contribution from man-made sources of uranium-238 and radium-226 remaining after a site cleanup could elevate indoor concentrations of radon-222 above 4 pCi/l.

Several states are pursuing regulatory options to mitigate radon exposure. Some states have already enacted laws that require school testing and disclosure of potential radon problems in real estate transactions. Many states and local jurisdictions are implementing or considering regulations that require radon-resistant new construction. Sometimes, new homebuilders voluntarily provide radon disclosure forms in their business transactions. Congress is also considering the mandatory testing of schools located in radon priority areas and federal buildings, disclosure of information about radon during real estate transfers, and minimum radon-reduction measures for new constructions.

C. PROPOSED IMPLEMENTATION GUIDANCE

EPA is providing in this section IV.C. of the preamble for consideration by the public, some recommendations for implementing the rule that are not required by its standards. In this section of the preamble, EPA will be referencing existing and future guidances that are currently under development. EPA believes that these guidances will provide "work practices" such as remedial methods and remedial objectives for various site circumstances, that will facilitate site remediations on a consistent basis that is even more protective than those mandated by the rule. EPA expects in the future to be developing additional guidance that will further facilitate compliance with the remediation of radioactively contaminated sites. When developing future guidance, EPA plans to review those guidances already existing, including those mentioned in this section.

1. Guidance on Ground Water

EPA is recommending that the implementing agencies use EPA's Ground-Water Protection Strategy as guidance when determining the appropriate remediation for contaminated ground water at AEA sites. EPA's Ground-Water Protection Strategy establishes different degrees of protection for ground waters based on their vulnerability, use, and value. The goal of EPA's proposed approach is to return usable ground waters to their beneficial uses within a timeframe that is reasonable given the particular circumstances of the site. Assessing the physical characteristics of the affected aquifer and the current and potential uses of the ground water is the first step in deciding the remediation goal the most appropriate remediation method, and the timeframe, for achieving these goals. A determination is made as to whether the contaminated ground water is a current or potential source of drinking water. This determination should be made by considering the physical characteristics of ground water quality, potential aquifer yield, and current ground water uses. EPA would prefer that potential future ground water uses be determined from the state classification of the contaminated ground water. In the absence of a state classification, or where the state classification does not indicate future use of ground water, then EPA's classification system should be used on a site specific basis. (Guidance for making determination with EPA's classification system is available in "EPA Guidelines for Ground-Water Classifications" (Final Draft, December 1986).)

Special ground water (EPA Class I) is both highly vulnerable to contamination because of the hydrological characteristics of the areas in which it occurs, and is characterized by either of the following factors: the ground water is irreplaceable, since no reasonable alternative source of drinking water is available to substantial populations (sole source aquifer), or; the ground water is ecologically vital, since the aquifer provides the base flow for a particularly sensitive ecological system that, if polluted, would destroy a unique habitat.

Current and potential sources of drinking water and water having other beneficial uses includes all other ground water that is currently used (EPA Class IIA), or is potentially available (EPA Class IIB), for drinking water, agriculture, or other beneficial use.

Ground water not considered a potential source of drinking water and of limited beneficial use (EPA Class IIIA and Class

IIIB) has a total dissolved solids levels over 10,000 milligrams per liter (mg/l), or is otherwise contaminated by naturally occurring constituents or human activity that is not associated with the site. Class III also includes ground water that is not available in sufficient quantity at any depth to meet the needs of an average household.

Class IIIA includes ground water that is interconnected to surface water or adjacent ground water that potentially could be used for drinking water. Class IIIB includes ground water that has no interconnection to surface water or adjacent aquifers.

Some states have developed and promulgated their own ground water classification systems. It is generally expected that EPA would prefer deference to a State's classification system when determining remediation goals. In addition, State wellhead protection programs developed pursuant to § 1428 of the SDWA, may influence classification of ground water. For example, if a radioactively contaminated site is within a wellhead protection area, Class IIA ground water may be treated as special (EPA Class I, or state equivalent). (Guidance which describes the criteria for establishing wellhead protection areas is available in "The Guidance for Applicants for State Wellhead Protection Program Assistance Funds Under the Safe Drinking Water Act", Office of Ground-Water Protection, June 1987.)

For ground waters that are current or potential sources of drinking water (EPA Classes I and II, or equivalent state classification), remediation must ensure that, if technically practicable, MCLs are not exceeded for 1,000 years. A determination that restoration of ground water to MCLs is technically impracticable, is to be made on the basis of engineering considerations. (Guidance for making this determination is available in EPA OSWER Directive 9234.2-25 "Guidance for Evaluating the Technical Impracticability of Ground-Water Restoration", October 4, 1993.) If restoration of ground water is determined to be technically impracticable, then institutional controls (e.g., prohibitions on well drilling, deed restrictions, etc.) and engineering controls (e.g., plugging of existing wells, or containment methods that prevent further contaminant migration), should be utilized to ensure protection of human health and the environment.

EPA's preference is for more aggressive remedial methods and shorter restoration timeframes, when practicable, for special ground waters (EPA Class I, or equivalent state classification) and contaminated ground waters that are currently, or likely in the near-term to be, the source of a drinking water supply (EPA Class II A and IIB, or equivalent state classification). The actual restoration timeframe will be determined by hydrogeological conditions, specific radioactive contaminants at a site, and the size of the contaminant plume. If there are other readily available drinking water sources of sufficient quality and yield that may be used as an alternative water supply, the preference for more aggressive restoration of the contaminated ground water may not be appropriate.

More aggressive remedial methods and shorter restoration timeframes are also favored in situations where other potential drinking sources are insufficient to meet expected demand. More aggressive restoration may also be appropriate where the institutional or engineering controls to prevent the utilization of radioactively contaminated ground water for drinking water purposes are not clearly effective or reliable. Institutional controls will usually be used as supplementary protective measures during implementation of ground water remedies.

For ground water that is not a current or potential source of drinking water (EPA Class III, or equivalent state classification), restoration of contaminated ground water to MCL levels, or to remediation of other media to avoid exceeding the MCLs, is not required. The beneficial use of ground water (e.g., agricultural or industrial use), if any, is determined; and the remediation approach will be tailored for returning the ground water to that designated use. For ground water that is not a current or potential source of drinking water but is hydrologically connected to potential drinking waters or to surface water ecosystems (EPA Class IIIA) the remediation approach will ensure that MCLs for radionuclides are not exceeded in the interconnected drinking water resources, and should ensure the protection of the interconnected surface waters. Institutional and engineering controls should be utilized to ensure protection of human health and the environment.

The Agency has been further developing its overall ground water protection strategy. In January 1990, EPA completed development of a strategy to guide future EPA and State activities in ground water protection and cleanup. Two papers were developed by an Agency-wide Ground-Water Task Force and were issued for public review: an EPA Statement of Ground-Water Principles and an options paper covering the issues involved in defining the Federal/State relationship in ground water protection. These papers and other Task Force documents have been combined into an EPA Ground-Water Task Force Report: "Protecting The Nation's Ground Water: EPA's Strategy for the 1990's" (EPA 21Z-1020 July 1991.)

This report sets forth an effective approach for protecting the Nation's ground water resources. The approach will be reflected in EPA policies, programs, and resource allocations and is intended to guide EPA, State and local governments, and other parties in carrying out ground water protection programs. The Agency has also issued "The Final Comprehensive State Ground Water Protection Program Guidance" (EPA 100-R-93-001 December 1992). This document provides guidance to

States for defining reasonably expected uses of their ground water. It is expected that in the future more States will be defining uses of their ground water.

2. Guidance on Soil

EPA is not proposing specific requirements for the remediation of soil in this rulemaking. The Agency is proposing that exposures from radionuclides in soil be included among the pathways being addressed by the standards described in § 196.04 of subpart A. However, the Agency has developed radionuclide soil concentrations (RSCs) which correspond to a risk level of 1×10^{-4}, and which under most circumstances should facilitate the setting of a cleanup level at a site for: the remediation of soil contaminated with radionuclides, and; the prevention of future contamination of other media to unacceptable levels (e.g., the exceedance of MCLs for radionuclides in groundwater) from residual radioactivity in soil. The Agency has developed one set of RSCs for a site where the intention is release for unrestricted (e.g., residential) land use, and another for a site that when released is restricted to industrial/commercial uses. (Further discussion of the RSCs, including the methodology used in the development of RSCs and how RSCs may be adjusted to compensate for site-specific circumstances, is available in the Background Information Document for this proposed rulemaking)

The RSCs are risk-based levels that were developed to facilitate, the setting of soil cleanup levels on a site-specific basis, that will attain the standards being proposed by this rulemaking. The RSCs should be most suitable for developing cleanup levels at a site, when the exposure pathways of concern and site conditions at the site are equivalent to the default values employed for each of the sensitive input parameters (e.g., fate and transport, potential exposure pathways of concern, and human or environmental receptors) that were used to develop the RSC for each radionuclide. The RSCs were developed using default values that reflect very conservative assumptions concerning the sensitive input parameters, which means that at the majority of sites, a concentration of a particular radionuclide at its RSC level will actually result in a less than 1×10^{-4} risk level. There does exist the potential that at some sites, the default values which were employed for the sensitive input parameters used to develop RSCs may not be as conservative as warranted by site conditions. For example, at a specific site there may exist: potential ecological concerns; unusual site conditions (e.g. unusually high fugitive dust levels, very shallow groundwater, karst topography), or; other likely human exposure pathways that were not considered in development of the RSCs (e.g., site-specific food pathways).

When assessing the appropriateness of using the RSCs to set a cleanup level at a particular site, the implementing agencies should compare the relatively conservative sensitive input parameters used in the development of the RSCs, to data gathered from the site (i.e., site sampling data, historical records, aerial photographs, and site hydrogeologic information). The RSCs should be suitable for use in setting cleanup levels at sites, when conditions at the site are consistent with the default sensitive input parameters used in the development of the RSCs. However, if an analysis of actual site conditions indicates that the site-specific values for sensitive input parameters at the site differ significantly from the default values employed in the methodology used to develop the RSCs, then the RSCs will need to be adjusted if used to set a cleanup level, which will attain at that site, the standards proposed in § 196.04. EPA has provided methodology for adjusting several of the default values for the sensitive parameters (i.e., unsaturated zone thickness, infiltration rate, Kd value) used to develop the RSCs. The values for these parameters may be adjusted to be made either more conservative, or less conservative, depending upon conditions at the site. If the RSC methodology does not include a pathway that is a likely human exposure pathway at the site, then it may be sufficient to evaluate the risk from those exposure pathways that are not already considered in the RSC methodology, and add that risk to the risk level derived from using the RSC methodology. (Guidance which describes possible procedures for sampling is being developed in the "Site Investigation Manual", which is currently being developed by EPA in conjunction with DOE and NRC).

3. Guidance on Structures

EPA is not proposing specific requirements for the remediation of structures in this rulemaking. The Agency is proposing that exposure from radionuclides in structures be included among the pathways being addressed by the standards described in § 196.04 of subpart A. (Guidance which describes possible procedures for sampling is being developed in the "Site Investigation Manual", which is currently being developed by EPA in conjunction with DOE and NRC). EPA is also planning to develop guidance on methods to address structures during the cleanup process. During guidance development EPA plans to review existing NRC guidance (i.e., NUREG/CR-5849, PNL-7409, NUREG-1496, NUREG/CR-5512) that concern characterization of building material contamination.

4. Guidance on Surface Water

EPA is not proposing specific requirements for surface water protection in this rulemaking. The Agency is proposing that

exposure from radionuclides in surface water be included among the pathways being addressed by the standards described in § 196.04 of subpart A. However, the Agency does believe that there are sections of the CWA and SDWA which under some circumstances may facilitate the setting of remedial objectives for the: restoration of contaminated surface water, and/or; the prevention of future contamination of surface water from other sources (i.e., contaminated soil or groundwater).

Federal Water Quality Criteria (FWQC) are developed under § 304 of the CWA for evaluating toxic effects on human health and aquatic life. FWQC are non-enforceable guidelines that set concentrations of pollutants which, when published, were considered adequate to protect surface waters. The only FWQC established for radionuclides are as follows: 10 pCi/l for Strontium-90; 3 pCi/l for Radium-226, or; in excluding either of the first radionuclides, 1,000 pCi/l for gross beta activity. These FWQC were developed for farmstead uses and were not adjusted for drinking water use. (These FWQC were originally issued in "Water Quality Criteria: Report of the National Technical Advisory Committee to the Secretary of the Interior", Federal Water Pollution Control Administration, April 1, 1968, reprinted 1972 by the U.S. EPA.) The final values of FWQC that protect human health may differ from MCLs because FWQC take into consideration a bioconcentration factor and fish ingestion factor, while MCLs take into consideration economic and treatability factors. Also, many FWQC have not been recently updated. (Guidance which describes factors to consider when FWQC and when determining cleanup levels that are based on FWQC is available in "The WQC Standards Handbook", U.S. EPA, December 1983.)

State Water Quality Standards (WQS) are developed under § 303 of the CWA to use in the implementation of the National Pollutant Discharge Elimination System (NPDES) program. FWQC are used or considered by States in setting their WQS. State WQS may be either numeric or narrative, and may be designated for a particular water body. At least 35 States have developed WQS for radionuclides, of these 11 States have WQS that are adjusted for drinking water use.

Where surface waters serve as an actual or potential drinking-water source, the Agency would usually prefer that the following standards be attained: State WQS that are either designated for drinking-water use and are more stringent than Federal standards (MCLs or FWQC), or specific to the uses of that water body; or, if none, MCLs; or, if none, FWQC adjusted for drinking-water use. Where surface water is not considered an actual or potential drinking-water source, the Agency would usually prefer that the following standards be attained: State WQS; or, if none, FWQC.

5. Air

[To be added.]

D. PUBLIC PARTICIPATION

EPA is proposing in § 196.03(a) of subpart A of this proposed rulemaking, a specific public notice and comment process. EPA is also proposing in § 196.03(b) of subpart A, six situations in which the implementing agencies will be required to conduct the public notice and comment provisions of § 196.03(a). The requirements for public notice and comment commence when the implementing agency first decides that it intends to cleanup a site to the extent that it can be released for public use, and does not end until the site has been cleaned up to allow its release for residential use. EPA is also requiring public notice and comment whenever a decision is made concerning the future land use of the site.

EPA believes that there exists a general consensus that opportunities for earlier, direct and regular community involvement would enhance the communities' participation throughout the cleanup process. EPA has found when conducting cleanups under CERCLA, that many communities near Superfund sites, including low income, minority and Indian communities, feel that they are not provided with the opportunity to fully participate in the cleanup process. These and other communities believe that the program does not address local concerns adequately when addressing risk or determining the method and level of cleanup, particularly with respect to future use of land. The public is often skeptical of the government's willingness to give serious consideration to community concerns. Affected stakeholders sometimes voice concern that opportunities for their involvement in site activities come too late in the process and that their input has little impact on cleanup decisions. In this rulemaking, EPA is proposing public notice and comment requirements and processes that will address these concerns.

EPA has proposed these requirements in accordance with the provisions of the Atomic Energy Act of 1954 and the Administrative Procedures Act of 1946, as amended. (For a discussion of these statutory authorities, see Section III.C of this preamble.) This rule reflects the Agency's intention to expand and improve the level and forms with which it communicates with affected communities and to increase efforts to involve the community in environmental policy-making.

EPA recommends that the implementing agencies establish at suitable sites, a community group to advise in the selection of a remedy that is considered appropriate by that community. These community groups should be formed after issuing an intention to remediate public notice. If a community group is able to reach a consensus on a significant remedy selection issue,

particularly on future land use of the site, their recommendations should be given substantial weight. The implementing agencies should prepare a written explanation when they make decisions that are inconsistent with the SSABs recommendations on a significant issue, such as land use.

EPA recommends that the implementing agencies should establish no more than one community group per site, however, as community groups should be used to complement, not duplicate or supplant, broader site-level public involvement initiatives such as community relations under CERCLA. Furthermore, community groups should only be established as needed when no advisory committee is in place (e.g., Community Work Groups for CERCLA actions) and an affected local, state, tribal, or federal government entity requests the establishment of an community group, or at least 50 residents of the community or region in which a site is located sign a petition requesting the formation of a community group.

When developing further guidance, EPA plans to review material developed for both the Federal Facilities Environmental Restoration Dialogue Committee (FFERDC) and the Superfund Reform Act which emphasize the establishment of citizen groups from the community affected by the site cleanup.

E. ASSURANCE OF STANDARD REQUIREMENTS

1. Active Control Measures

EPA is proposing in § 196.04(c) of subpart A of this rulemaking, that sites which are not remediated for unrestricted residential use, may be released with active control measures that are intended to assure that exposed individuals at sites released under restrictions receive no more of a dose than sites released without restrictions. Active control measures must also be used as part of a remedial action to prohibit exposure to drinking water in which MCLs for radionuclides are exceeded, as required by § 196.23(c)(1) of subpart B. The implementing agencies should also utilize active control measures, prior to and during the conduct of remedial actions, as appropriate, to limit exposures from radionuclides.

Active control measures will include all institutional controls and those engineering controls which rely on institutions and continued expenditures for active maintenance. When planning remedial actions that involve active control measures, the implementing agencies should determine: the type of active control measures to be used; the existence of the an authoritative entity (e.g., governmental organization) to implement the active control measure, and; the appropriate entity's resolve to implement the active control measure. The implementing agencies should attain assurances from the authoritative entity that active control measures will continue to be implemented, to ensure to the greatest extent possible, compliance with the requirements of this part.

EPA expects that one active control measure the implementing agencies and local communities will employ to return some remediated sites to productive use, for those sites that are not expected to be used for residential purposes, will be to release these sites with land use restrictions that limit the released site to industrial or commercial uses. The site that is released for use by the implementing agency might still be owned by the agency but leased to businesses, or land use restrictions may be maintained by the use of institutional controls such as deed restrictions, deed notices, and deed records which either prohibit certain kinds of site uses or, at a minimum, notify potential owners or land users of the presence of hazardous substances remaining on site at levels that are not protective of all uses. For example, a remedial action may result in a site that is protective for industrial/commercial land use, with low levels of hazardous substances remaining on site. Business would be able to operate on-site after the remedial action. However, institutional controls generally need to be put in place to ensure that the land is not used for other less restrictive purposes, such as for residential purposes, and/or to alert potential buyers of the property to any remaining radioactive material.

2. Assurance requirement

EPA is requiring, in § 196.05 of subpart A and § 196.24 of subpart B, that the implementing agencies conduct reviews at least every X years for those sites where radionuclide concentrations at the site are above levels that will not allow unrestricted use. At those sites where remedial actions will take X years or more to reduce radionuclide concentrations to a level that will allow unrestricted use, the Agency is encouraging the implementing agencies to conduct reviews at least every X years.

The implementing agencies should develop a X-Year Review Report for each X-year review. The Report should include a: summary of site conditions; summary of remedial action selected; summary of remedial action performed; description of post-remedial action activities; scope and nature of X-year review; summary of results of the review; summary of actions taken or proposed on the basis of the review, and; expectation for the scope and nature of future reviews. Before commencing a X-year review, the implementing agencies should inform the public of its determination that a X-year review is required, the

planned scope of such reviews, the location of the report on the review, on-site review activities, actions taken based on any review, and any location where the X-Year Review Report will be accessible to the public.

X-year reviews are intended to evaluate whether the remedial action remains protective of public health and the environment. The focus of the X-year review will depend on the original goal of the remedial action. For example, if protectiveness is being assured through engineering controls (e.g., containment with a cap) and institutional controls, the review should focus on whether the cap remains effective and the institutional controls remain in place and are being complied with. A X-year review should be commenced in sufficient time to assure completion of the review within X years of initiation of the remedial action (i.e., award of the contract for remedial action). If an implementing agency determines during the course of an X-year review that the remedial action is not remaining protective of public health and the environment, public notification is required by § 196.03(b)(5) of subpart A.

The implementing agencies may cease conducting X-year reviews when the radionuclide concentrations are reduced so that the standards for unrestricted residential use, as described in § 196.04(a) of subpart A, as well as § 196.23(a) of subpart B, have been met. For example, if an improvement in remedial technology results in a site that was previously released with land use restrictions, subsequently being remediated to a level that allows unrestricted residential use, then X-year reviews for that site would no longer be necessary.

V. CONSIDERATION OF WASTE MINIMIZATION/POLLUTION PREVENTION (WM/PP)

Today's proposed rule establishes standards to foster expeditious, efficient cleanup of sites contaminated with radioactive material in a manner that protects human health and the environment. Minimizing the generation of radioactive wastes and pollution prevention are critical components in achieving this target goal. This section presents EPA's policy and recommended approaches for incorporating waste minimization and pollution prevention objectives as part of site cleanup activities.

A. DEFINITION OF WM/PP FOR RADIOACTIVE WASTE

In the last decade environmental advocates, industries, regulatory agencies (including EPA), and the public at large have recognized that it is better to avoid creating pollutants in the first place than to expend effort and resources in treating and disposing of them once they have been generated. This approach to environmental protection is widely referred to by the related terms "waste minimization" and "pollution prevention" (WM/PP). The term "source reduction" has also been applied. Practically speaking, WM/PP has different meanings in different parts of the radionuclide life cycle. In radionuclide production and use, WM/PP usually means the same as it does in general i.e., reducing the amount or the toxicity of a waste or pollutant. On the other hand, because radionuclides generally cannot be destroyed, WM/PP in site cleanup and waste management generally refers only to reducing, by concentration or segregation, the *volume* of contaminated media (soil, water, biological matter, structural materials, etc.) that require disposal.

The literature contains a number of definitions of these terms, but all share common elements. The first is that they refer to reducing the amount or the toxicity of potential contaminants. Another is that they exclude end-of-pipe treatments. In this preamble, EPA adopts the definitions contained in the RCRA Waste Minimization Action Plan:

- "Source Reduction" includes equipment or technology modifications; process or procedure modifications; reformulation or redesign of products; substitution of raw materials; and improvements in housekeeping, maintenance, training, or inventory control. Source reduction does not include recycling, treatment, or disposal.
- "Waste Minimization" is source reduction plus most recycling and reuse.
- "Pollution Prevention" is synonymous with source reduction.

B. MANDATE FOR WM/PP

EPA's mandate for pursuing waste minimization and pollution prevention as strategy for environmental protection is derived from several sources:

The Pollution Prevention Act of 1990 (PPA, Public Law 101-508 [***Need U.S.C. cite***], November 5, 1990) declares national policy, with top priority given to the prevention or reduction of pollution at the source, followed by recycling. The Act does not, however, prescribe regulations or compliance goals.

The Administrator's policy statement of June 15, 1993, makes WM/PP a cornerstone of EPA's activities: "We must build

pollution prevention into the very framework of our mission to protect human health and the environment." Some specific provisions of the policy statement include:

- -- Emphasizing WM/PP in developing regulations, permitting, inspection, and enforcement.
- -- Integrating WM/PP into state, local, private, and federal partnerships; public information and the right to know; technological innovation; and new legislation.

The RCRA Waste Minimization Action Plan of May 1992 describes many EPA activities in which WM/PP has become a prime focus. The plan states, "EPA firmly believes that . . . pollution prevention . . . must be a central component of Agency programs [and] the Agency is moving to incorporate pollution prevention into every facet of its program." Furthermore, Executive Order 12856, issued by President Clinton on August 6, 1993, limits the federal government's acquisition of toxic chemicals. Under this order, each federal agency must (among other things) develop a written pollution prevention strategy that reflects the Agency's commitment to incorporating pollution prevention through source reduction, in both its facility management and its acquisition procedures.

C. HOW THE PROPOSED RULEMAKING MEETS THE MANDATE

The rule that EPA is proposing meets the mandate to implement WM/PP. It does so by setting the standard in terms of a limiting dose that must be achieved at each site, while not specifying the means by which it must be achieved. This performance-based approach will, through market mechanisms, encourage the development of innovative methods for cleaning up sites. Because WM/PP methods, such as concentrating or segregating radioactive materials, promise to be among the most efficient, EPA anticipates that they will feature prominently among the innovations to be developed (see Section VI.D below). EPA considered a technology-based cleanup standard but rejected it in part because it could inhibit the development of innovative cleanup and management technologies (see Section IV.B.7 above).

There is evidence that innovative WM/PP methods are already being developed for use in cleaning up and managing radioactive wastes. One example is the trend in some hospitals to switch from using hazardous radium-226 in needles to shorter-lived, less hazardous iridium-192 or cesium-137. Techniques such as replacing long-lived isotopes with short-lived ones or with non-radioactive substances and storing short-lived radioisotopes until they decay are discussed in various technical manuals. EPA expects that its performance-based standard will further encourage the development and adoption of WM/PP methods.

D. MARKET FORCES AND INCENTIVES FOR WM/PP AS A RESULT OF THE PROPOSED RULEMAKING

Under the common assumption that companies seek to maximize profits, any technological development that increases the productivity of a process or an industry will eventually be adopted as a result of market forces alone. Although not many economic evaluations of WM/PP technologies have been done, there is evidence that some WM/PP measures, properly implemented, can reduce costs. Du Pont, for example, has announced that its voluntary program of improved environmental packaging has cut 150 million pounds, or 20 percent, of packaging wastes from shipments to customers. This translates into a cost savings of $15 million annually. Whyco Chromium, Inc., a company specializing in the plating of small parts, reported a 25 percent saving in operating costs (amounting to about $1 million per year) after developing a substitute for cadmium as a corrosion-resistant finish. Other cases of savings resulting from WM/PP are documented in various EPA publications.

Experience with WM/PP as applied to the production and use of radionuclides and the cleanup and management of radioactive wastes is even more limited than in the case of chemical pollutants. Nevertheless, it is likely that WM/PP measures will be developed for radiation applications that will reduce costs overall, and hence will achieve market acceptance without the need for regulatory incentives.

Apart from the potential of WM/PP measures in particular to reduce costs, there is evidence that certain forms of environmental regulation in general tend to encourage the development of new products and processes. Ashford, et al. concluded that ". . . product regulations tend to call forth product innovations, that component or pollutant regulations tend to elicit process innovations, and that the stringency of regulation is an important determinant of the degree of technological innovation." This conclusion was supported by case studies of innovations resulting from the regulation of PCBs, chlorofluorocarbons, metals in paint, vinyl chloride, and other substances.

Finally, EPA expects that by imposing a uniform cleanup standard on many categories of contaminated sites, the proposed rule will encourage the development of new waste cleanup technologies. This is because developers and manufacturers of such technologies will be able to design for a single, large market in which all customers have similar requirements, rather than having to tailor their products to a variety of site-dependent specifications.

E. POTENTIAL BENEFIT OF WM/PP FOR RADIOACTIVE WASTES COMPARED TO CHEMICAL WASTES

WM/PP methods may offer greater benefits in the case of radioactive wastes than they do in the case of chemical wastes. This is because most chemical wastes can be destroyed or rendered harmless through treatments such as incineration or chemical reaction. For such wastes, WM/PP is merely an alternative (albeit a preferred alternative) to treatment. Radionuclides, however, cannot be destroyed or rendered benign by such methods. The only "treatments" available for radioactive wastes are various forms of isolation, concentration, and storage. Therefore, the only method for actually reducing the amount of radionuclides disposed of is to avoid, as much as possible, their manufacture and use in the first place.

VII. IMPACT ANALYSES

A. EXECUTIVE ORDER 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether a regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The order defines "significant regulatory action" as one that is likely to result in a rule that may:

- 1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector or the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- 2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- 3. Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- 4. Raise novel legal or policy issues arising out of legal mandates, the Presidents priorities, or the principles set for the Executive Order.

Pursuant to the terms of Executive Order 12866, EPA has determined that this rule is a "significant regulatory action" because the annual effect on the economy will be greater than $100 million. As such, this action was submitted to OMB for review.

When an agency submits a significant regulatory action for OMB review, the Order sets forth certain information that must be provided. This information includes a description of the need for the regulatory action, how the regulation will meet that need, and an assessment of the potential costs and benefits of the regulatory action. The agency must also provide an explanation of how the action is consistent with a statutory mandate, promotes the President's priorities, and avoids undue interference with state, local, and tribal governments. EPA has compiled this information in the Regulatory Impact Analysis for this proposed rule.
[*Insert brief discussion of RIA conclusions*]

Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. REGULATORY FLEXIBILITY ANALYSIS

The Regulatory Flexibility Act of 1980 requires each federal agency to perform a Regulatory Flexibility Analysis for all rules that are likely to have a "significant impact on a substantial number of small entities."

[***Remainder to be developed based on RIA analysis.***]

C. PAPERWORK REDUCTION ACT

The information collection requirements contained in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. § 3501 et seq.). EPA has prepared an information collection request for this proposed rule, a copy of which can be obtained from . . . .

Recordkeeping and reporting burden for this collection of information is stated to average NN hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and compiling and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, PM-XXX, U.S. Environmental Protection Agency, 401 M St.,

SW., Washington, DC 20460; and the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in the proposed rule.

List of Subjects
[***To be developed***]